



EUROPEAN
UNIVERSITY AT
ST. PETERSBURG

Пандемия Covid-19: данные популяционных исследований в Санкт-Петербурге, Россия

Антон Барчук

Конфликт интересов

Ассоциированный профессор АО "Полиметалл" по популяционным медицинским исследованиям

Институт междисциплинарных медицинских исследований Европейского университета в Санкт-Петербурге

Магистратура Public Health Sciences, Университет ИТМО

ФГБУ "НМИЦ онкологии им. Н.Н. Петрова" Минздрава России

Personal fees from AstraZeneca, MSD, and Biocad outside the presented work and before 2021.

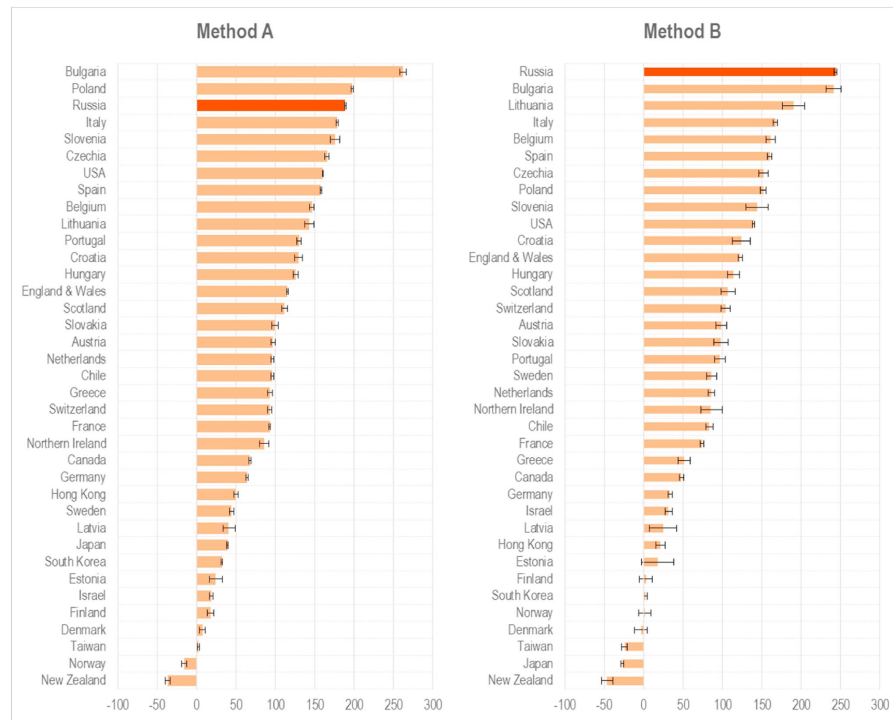
Cancer Epidemiology

IPPE Tampere University

Избыточная смертность

Россия ~ 1.2 млн человек
или ~830 на 100,000

Финляндия ~ 5 700 человек
или ~100 на 100,000



Кто победил в России?

Cons:

Коронавирус

Лаборатории и производители неэффективных лекарств

Pros:

Safety and efficacy of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine: an interim analysis of a randomised controlled phase 3 trial in Russia



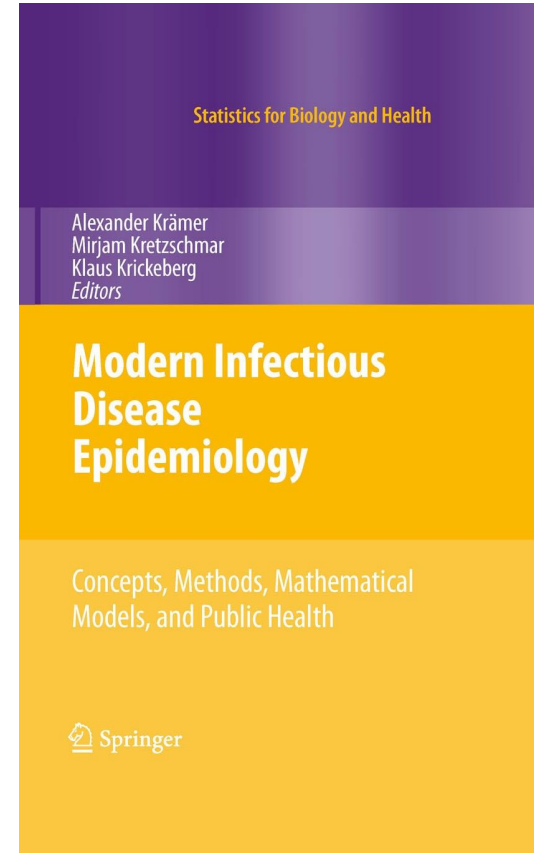
Denis Y Logunov*, Inna V Dolzhikova*, Dmitry V Shcheblyakov, Amir I Tukhvatulin, Olga V Zubkova, Alina S Dzharullaeva, Anna V Kovyrshina, Nadezhda L Lubenets, Daria M Grousova, Alina S Erokhova, Andrei G Botikov, Fatima M Izhaeva, Olga Popova, Tatiana A Ozharovskaya, Ilias B Esmagambetov, Irina A Favorskaya, Denis I Zrelkin, Daria V Voronina, Dmitry N Shcherbinin, Alexander S Semikhin, Yana V Simakova, Elizaveta A Tokarskaya, Daria A Egorova, Maksim M Shmarov, Natalia A Nikitenko, Vladimir A Gushchin, Elena A Smolyarchuk, Sergey K Zyryanov, Sergei V Borisevich, Boris S Naroditsky, Alexander L Gintsburg, and the Gam-COVID-Vac Vaccine Trial Group†

Пандемия COVID-19

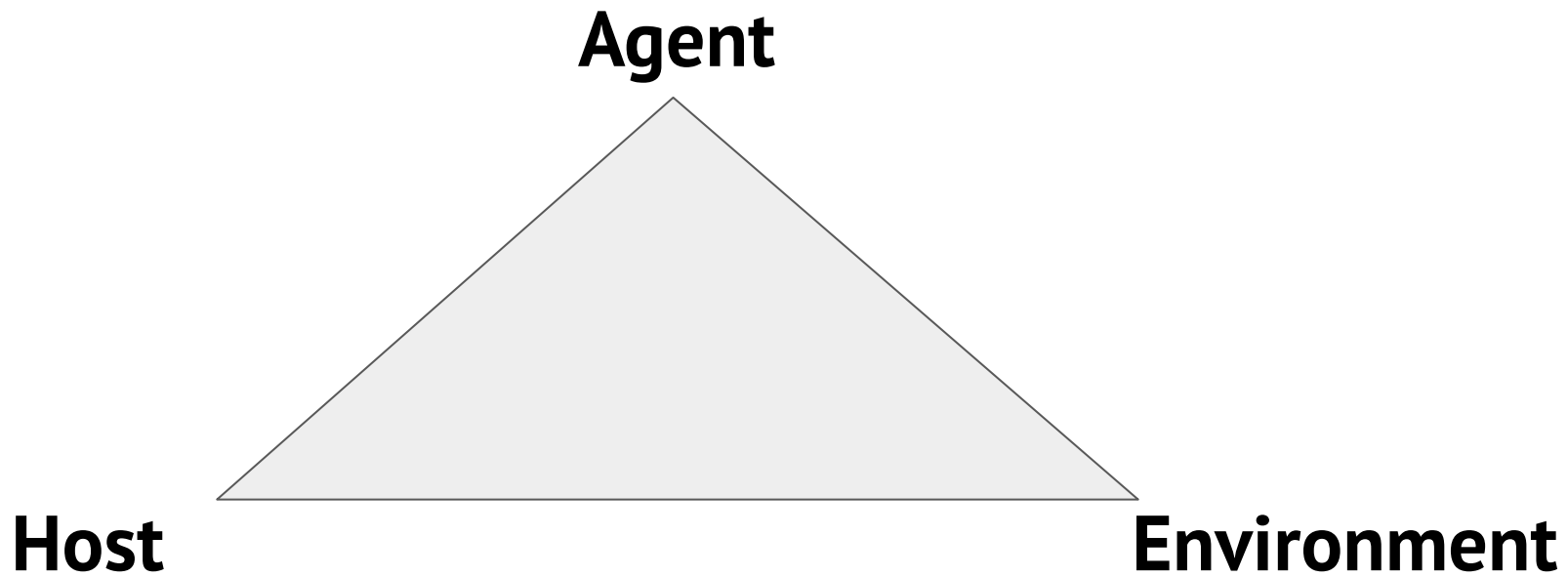
Был классический пример пандемии нового инфекционного агента.

Гетерогенная реакция населения/policy makers разных стран.

Эффективные вакцины уже во второй год пандемии.



Триада эпидемий



Agent: SARS-CoV-2

INVITED ARTICLE **VACCINES**

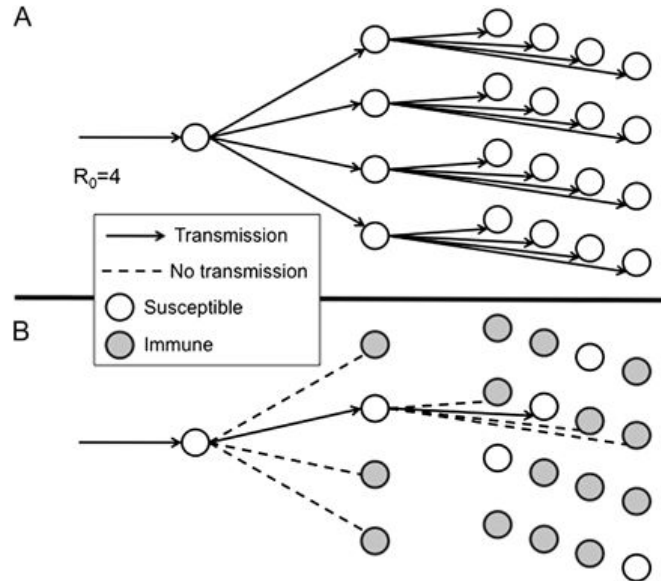
Stanley Plotkin, Section Editor

“Herd Immunity”: A Rough Guide

Paul Fine, Ken Eames, and David L. Heymann

Department of Infectious Disease Epidemiology, London School of Hygiene and Tropical Medicine, London, United Kingdom

The term “herd immunity” is widely used but carries a variety of meanings [1–7]. Some authors use it to describe the proportion immune among individuals in a population. Others use it with reference to a particular threshold proportion of immune individuals that should lead to a decline in incidence of infection. Still others use it to refer to a pattern of immunity that should protect a population from invasion of a new infection. A common implication of the term is that the risk of infection among susceptible individuals in a population is reduced by the presence and proximity of immune individuals (this is sometimes referred to as “indirect protection” or a “herd effect”). We provide brief historical, epidemiologic, theoretical, and pragmatic public health perspectives on this concept.



RESEARCH ARTICLE

COVID-19 pandemic in Saint Petersburg, Russia: Combining population-based serological study and surveillance data

Anton Barchuk^{1,2*}, Dmitriy Skougarevskiy¹, Alexei Kouprjanov³, Danil Shirokov⁴, Olga Dudkina⁵, Rustam Turun-zade⁶, Maria Sergeeva⁷, Varvara Tychkova⁸, Andrey Komissarov⁹, Alena Zhetukhina¹⁰, Dmitry Lizonov¹¹, Artur Isen¹², Ekaterina Pomerantseva¹³, Svetlana Zhikrivetskaya¹⁴, Yana Sofronova¹⁵, Konstantin Blagodatikhin¹⁶, Kirill Titsev¹⁷, Lubov Barabanova¹⁸, Daria Danilenko¹⁹

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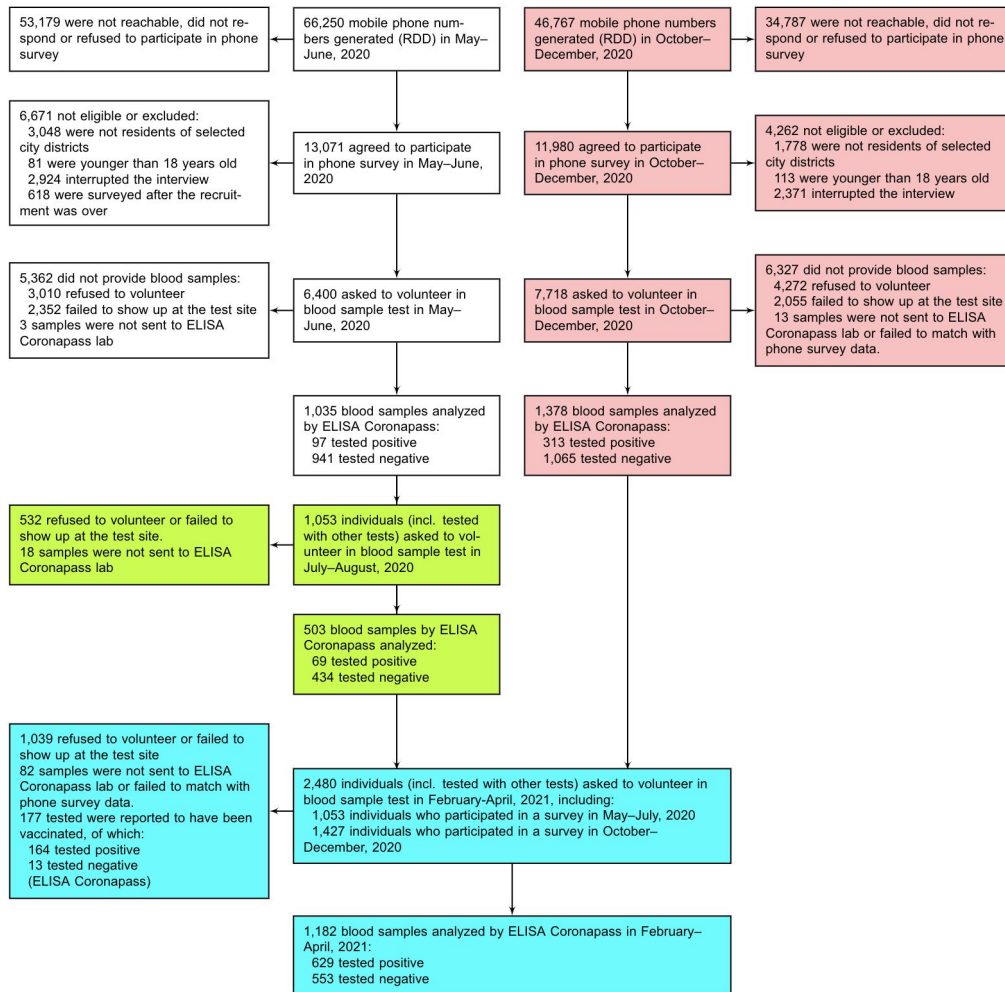
* abarchuk@eu.spb.ru



scientific reports

OPEN Seroprevalence of SARS-CoV-2 antibodies in Saint Petersburg, Russia: a population-based study

Anton Barchuk^{1,2*}, Dmitriy Skougarevskiy¹, Kirill Titsev¹⁷, Danil Shirokov⁴, Yulia Raskina¹, Anastasia Novikovskaya¹, Petr Talantov¹, Artur Isen¹², Ekaterina Pomerantseva¹³, Svetlana Zhikrivetskaya¹⁴, Lubov Barabanova¹⁸ & Vadim Volkov¹⁹





scientific reports

OPEN

Seroprevalence of SARS-CoV-2 antibodies in Saint Petersburg, Russia: a population-based study

Anton Barchuk^{1,2,3,4,5,6,7,*}, Dmitriy Skougarevskiy¹, Kirill Titaev¹, Danil Shirokov¹, Yulia Raskina¹, Anastasia Novkunkskaya¹, Petr Talantov¹, Artur Isaev¹, Ekaterina Pomerantseva¹, Svetlana Zhikrivetskaya¹, Lubov Barabanova¹ & Vadim Volkov¹

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Anton Barchuk^{1,2,3,4,5,6,7,*}, Dmitriy Skougarevskiy¹, Alexei Kouptianov¹, Danil Shirokov¹, Olga Dudkina¹, Rustam Tursun-zade¹, Mariia Sergeeva¹, Varvara Tychkova¹, Andrey Komissarov¹, Alena Zhelezubina¹, Dmitry Lizonov¹, Artur Isaev¹, Ekaterina Pomerantseva¹, Svetlana Zhikrivetskaya¹, Yana Sofronova¹, Konstantin Blagoderzhikov¹, Kirill Titaev¹, Lubov Barabanova¹, Daria Danilenko¹

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Check for updates

Figure S1. Naïve and adjusted seroprevalence by study cross-section and week (ELISA Coronapass)

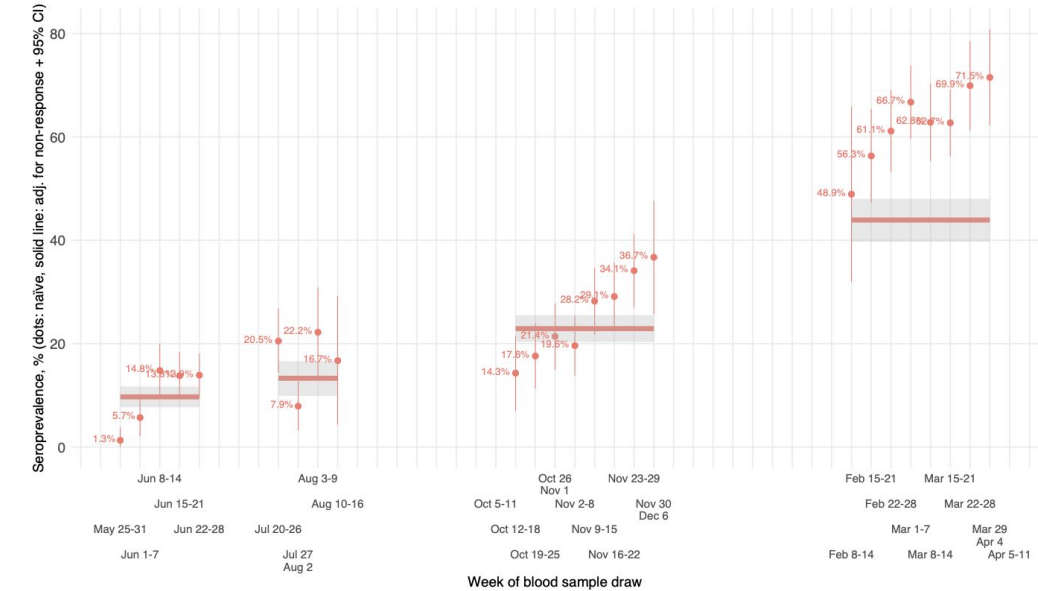


Table 1. Seroprevalence by study cross-section, ELISA Coronapass.

Serosurvey cross-section	N interviewed / N tested	Seroprevalence estimate		
		Naïve	Adjusted for non-response	Adjusted for non-response and test characteristics
(May 25, 2020—June 28, 2020)	5951 / 988	10.6 (8.7–12.5)	8.9 (7.1–10.8)	9.7 (7.7–11.7)
2 (July 20, 2020—August 8, 2020)	5951 / 474	15.2 (12.0–18.4)	12.2 (9.1–15.3)	13.3 (9.9–16.6)
3 (October 12, 2020—December 6, 2020)	7110 / 1322	23.2 (20.9–25.5)	21.0 (18.7–23.4)	22.9 (20.3–25.5)
4 (February 15, 2021—April 4, 2021)	13412 / 1140	53.2 (50.3–56.1)	40.4 (36.5–44.2)	43.9 (39.7–48.0)

Serological evidence of human infection with SARS-CoV-2: a systematic review and meta-analysis

Xinhua Chen, BSc * • Zhiyuan Chen, BSc * • Andrew S Azman, PhD * • Xiaowei Deng, MSc • Ruijia Sun, BSc • Zeyao Zhao, BSc • et al. [Show all authors](#) • [Show footnotes](#)

Open Access • Published: March 08, 2021 • DOI: [https://doi.org/10.1016/S2214-109X\(21\)00026-7](https://doi.org/10.1016/S2214-109X(21)00026-7)

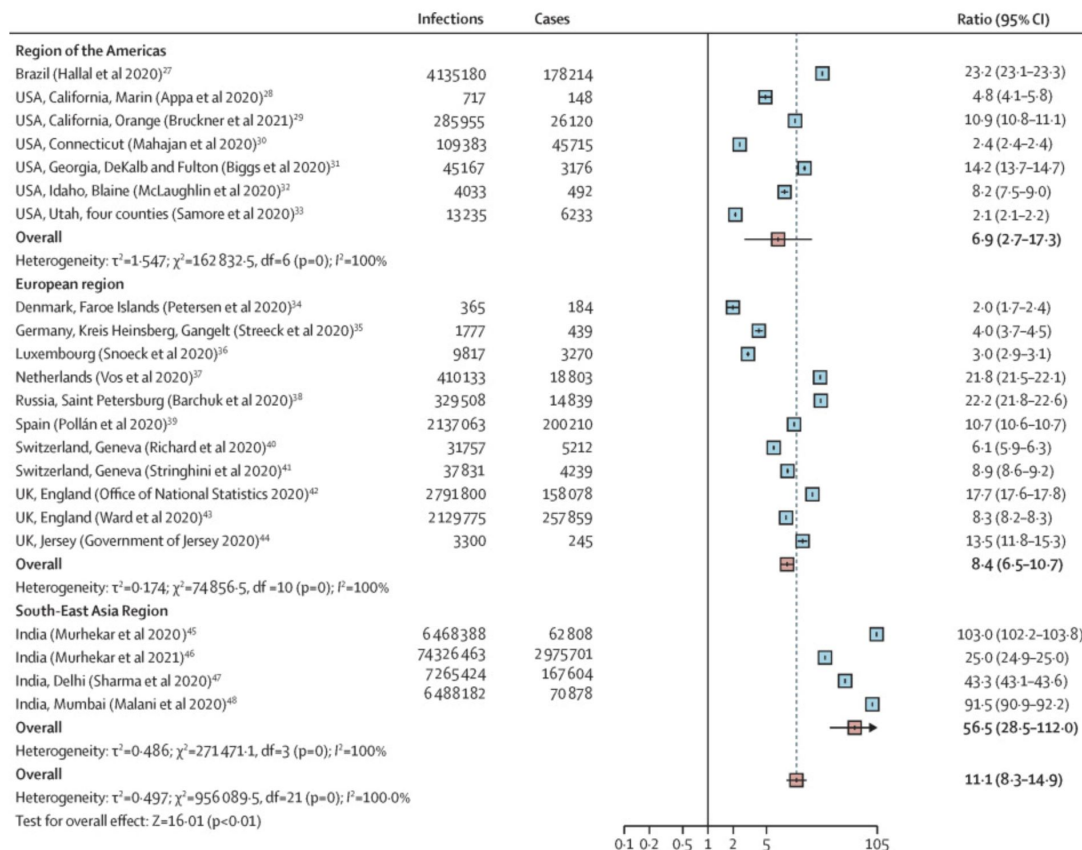


Figure 5 Estimated ratio of serologically detected infections to confirmed cases of COVID-19



RESEARCH ARTICLE
COVID-19 pandemic in Saint Petersburg,
Russia: Combining population-based
serological study and surveillance data

Anton Barchuk^{1,2*}, Dmitriy Skougarevskiy³, Alexei Koupritanov⁴, Danil Shirokov⁵,
Olga Dudkina⁶, Rustam Tursun-zade⁶, Mariia Sergeeva⁶, Varvara Tychkova⁶,
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¹ European University at St. Petersburg, St. Petersburg, Russia, ² Independent Researcher, St. Petersburg, Russia, ³ Clinic "Scandinavia" (LLC Ave-Peter), St. Petersburg, Russia, ⁴ Smorodintsev Research Institute of Influenza, St. Petersburg, Russia, ⁵ Center of Genetics and Reproductive Medicine GENETICO LLC, Moscow, Russia, ⁶ Human Stem Cells Institute, Moscow, Russia, ⁷ Pletzer National Research Medical Center of Oncology, Pesochy, St. Petersburg, Russia

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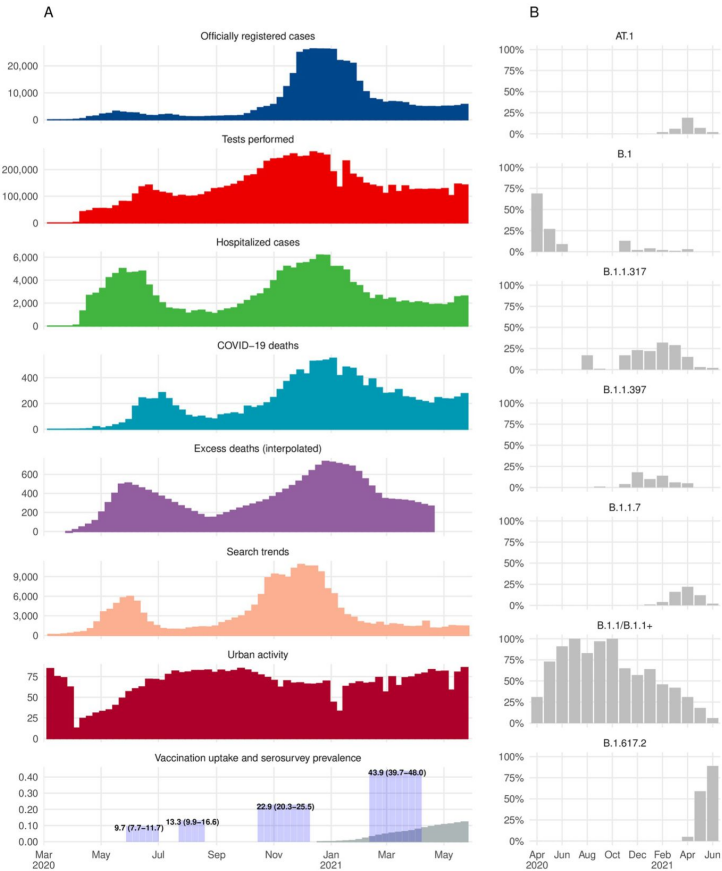


Fig 3. Combining available surveillance data to monitor the pandemic course in St. Petersburg during March-May 2020–2021. (A) Weekly data of officially registered cases, tests performed, hospitalised cases, COVID-19 deaths, interpolated excess deaths (from monthly data), search trends, urban activity, and vaccination uptake combined with seroprevalence estimates; (B) Monthly data on SARS-CoV-2 variants monitoring during April–June 2020–2021.

Agent: SARS-CoV-2

Infection fatality ratio

Alpha ?=? Delta ?>? Omicron

pre-Delta IFR in Petersburg - 0,86%

Table S2. Estimated IR/IFR across the study cross-sections from the Bayesian evidence synthesis model

population	only adult population								all population	
priors	weakly informative				non-informative				weakly inform.	
estimate	IR		IFR		IR		IFR		IR	IFR
deaths	official	excess	official	excess	official	excess	official	excess	excess	
1	9.28 (7.26–11.26)	9.22 (7.54–10.97)	0.29 (0.10–0.42)	1.01 (0.75–1.22)	9.41 (7.45–11.45)	9.30 (7.53–11.02)	0.27 (0.09–0.41)	1.01 (0.74–1.21)	9.22 (7.50–10.94)	0.83 (0.62–1.00)
2	12.73 (9.64–16.03)	13.30 (10.72–15.72)	0.40 (0.29–0.51)	1.05 (0.87–1.28)	12.91 (9.80–16.33)	13.35 (10.81–15.83)	0.39 (0.29–0.51)	1.05 (0.86–1.27)	13.28 (10.73–15.75)	0.87 (0.71–1.05)
3	22.78 (20.26–25.41)	22.84 (20.41–25.39)	0.48 (0.34–0.66)	1.05 (0.87–1.33)	22.82 (20.25–25.40)	22.87 (20.42–25.43)	0.48 (0.34–0.67)	1.06 (0.87–1.34)	22.84 (20.40–25.41)	0.87 (0.72–1.10)
4	43.84 (39.85–48.09)	43.64 (39.75–47.53)	0.61 (0.54–0.69)	1.04 (0.93–1.16)	43.80 (39.63–47.83)	43.65 (39.63–47.54)	0.61 (0.54–0.69)	1.04 (0.93–1.16)	43.64 (39.68–47.47)	0.86 (0.77–0.96)
Overall	8.69 (0.85–17.77)	8.74 (1.05–18.09)	0.43 (0.11–0.82)	1.04 (0.80–1.31)	23.38 (4.25–63.35)	23.29 (4.53–63.94)	0.50 (0.04–19.63)	1.04 (0.80–1.35)	8.79 (0.91–18.07)	0.86 (0.66–1.08)

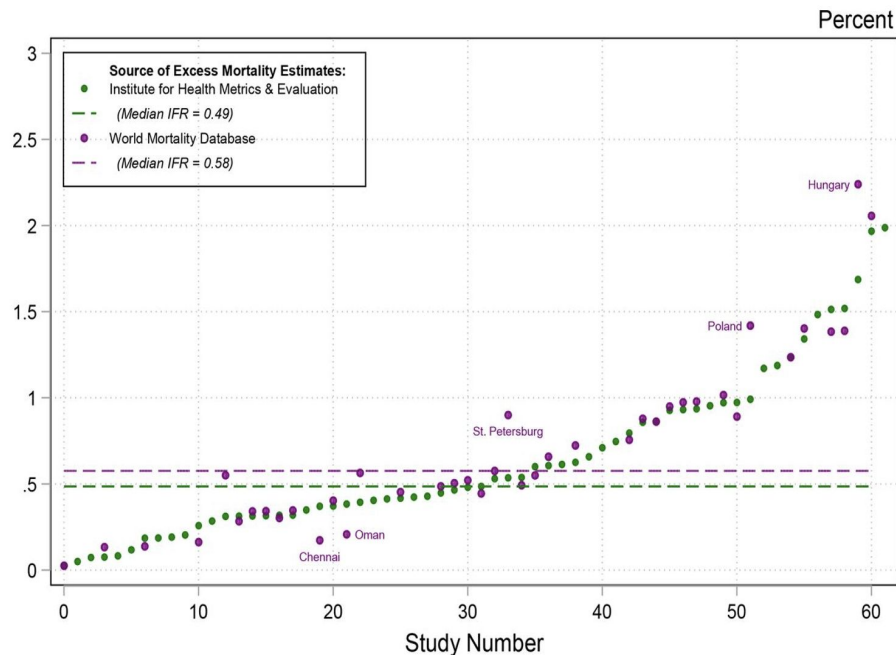
Летальность

population	only adult population								all population	
	weakly informative				non-informative				weakly inform.	
	IR		IFR		IR		IFR		IR	IFR
	official	excess	official	excess	official	excess	official	excess	excess	
1	9·28 (7·26–11·26)	9·22 (7·54–10·97)	0·29 (0·10–0·42)	1·01 (0·75–1·22)	9·41 (7·45–11·45)	9·30 (7·53–11·02)	0·27 (0·09–0·41)	1·01 (0·74–1·21)	9·22 (7·50–10·94)	0·83 (0·62–1·00)
2	12·73 (9·64–16·03)	13·30 (10·72–15·72)	0·40 (0·29–0·51)	1·05 (0·87–1·28)	12·91 (9·80–16·33)	13·35 (10·81–15·83)	0·39 (0·29–0·51)	1·05 (0·86–1·27)	13·28 (10·73–15·75)	0·87 (0·71–1·05)
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Agent: SARS-CoV-2

pre-Delta IFR in Petersburg -
0,86%

Excess mortality adjusted population IFRs. IFR, infection fatality rate.

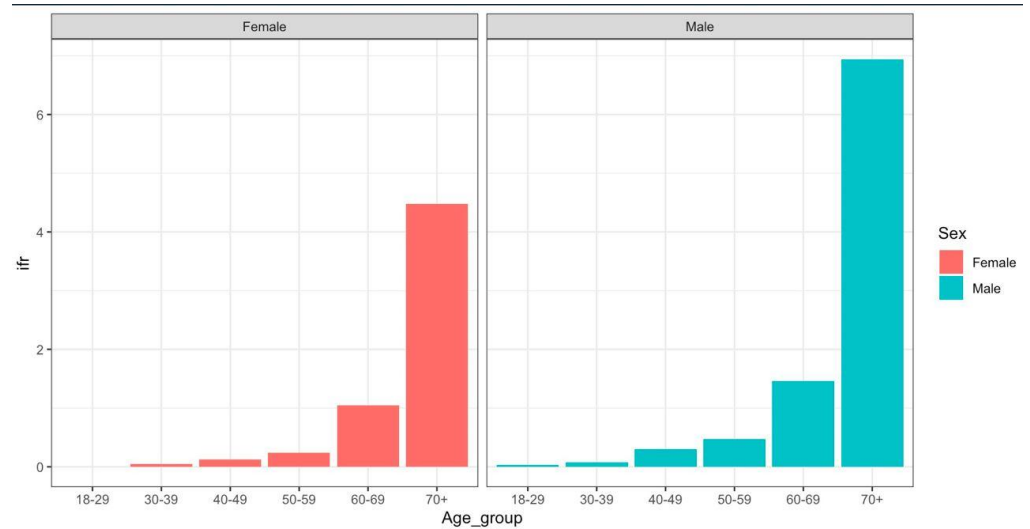


Andrew T Levin et al. BMJ Glob Health 2022;7:e008477

Host: Human

New VOCs tend to engage younger age groups

IFR is age-dependent



Длительность сероконверсии

PLOS ONE

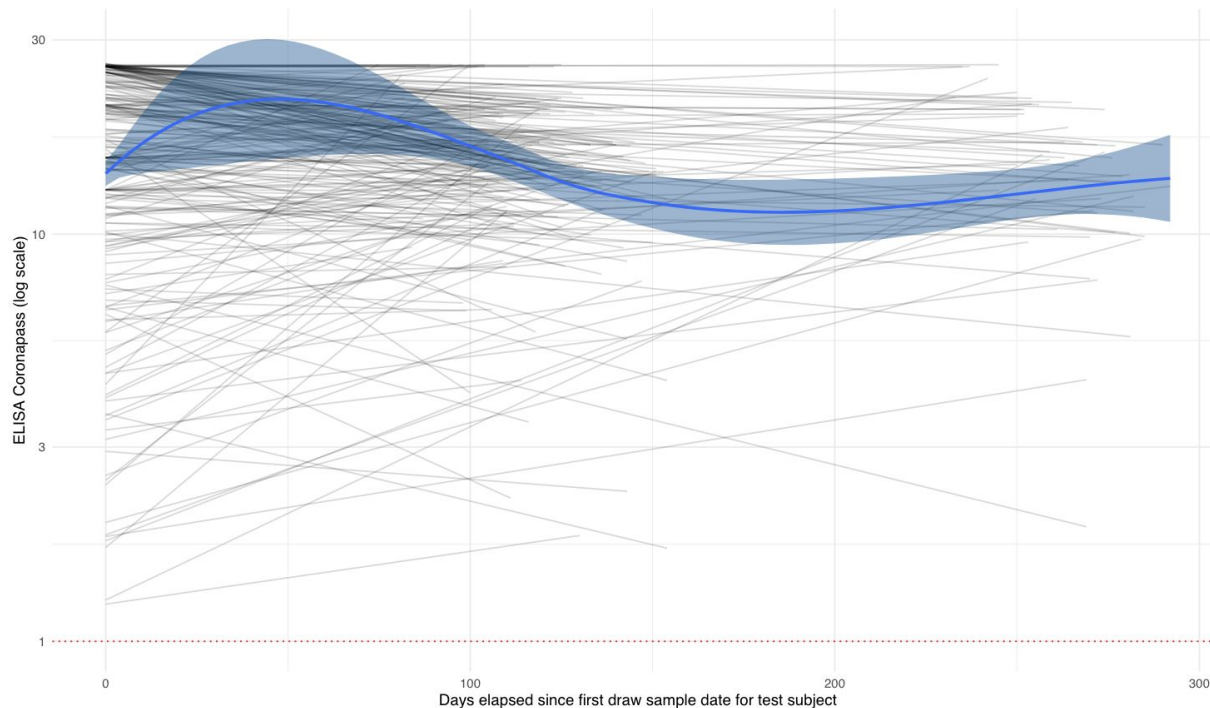
RESEARCH ARTICLE

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Anton Barabok^{1,2*}, Dmitry Blazgenovskiy¹, Ansel Kogutov¹, Denis Shirokov³, Olga Dudkina¹, Rustam Tursumzade¹, Maria Sergeeva⁴, Varvara Tyshkova¹, Andrey Komasev⁵, Alena Zhukhina¹, Dmitry Lobov¹, Artur Isen⁶, Ekaterina Ponomareva¹, Svetlana Zilovskaya¹, Yana Solonova⁷, Konstantin Blagodatikh¹, Kirill Tikhov¹, Lubov Barabanova¹, Daria Danilenko¹

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1 European University at St. Petersburg, St. Petersburg, Russia, 2 Independent Researcher, St. Petersburg, Russia, 3 Clinic "Sonderklinik" LLC Ave-Peter, St. Petersburg, Russia, 4 Simonsdorff Research Institute of Infection, St. Petersburg, Russia, 5 Center of Genetics and Reproductive Medicine (GNRC) LLC, Moscow, Russia, 6 Human Stem Cells Institute, Moscow, Russia, 7 Petrov National Research Medical Center of Oncology, Pashkovy, St. Petersburg, Russia

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Evaluation of the performance of SARS-CoV-2 antibody assays for a longitudinal populationbased study of COVID-19 spread in St. Petersburg, Russia

Anton Barchuk, Daniil Shirokov, Mariia Sergeeva, Rustam Tursunzade, Olga Dudkina 
Varvara Tychkova, Lubov Barabanova, Dmitriy Skougarevskiy, Daria Danilenko

First published: 03 June 2021 | <https://doi.org/10.1002/jmv.27126> | Citations: 7

The sensitivity for two local assays was equal to 91.1% (95%CI: 78.8-97.5) and 89.1% (95%CI: 76.4-96.4), CMIA Abbott's sensitivity was equal to 63.1% (95%CI 50.2-74.7)), with 100% specificity for all the tests.

Последний срез до Омикрона

Ноябрь:

У 83% участников сероопроса есть антитела к новому коронавирусу
(95%CI:80,6% до 85,5%)

Среди невакцинированных участников исследования коронавирусом переболели 78%.

Environment

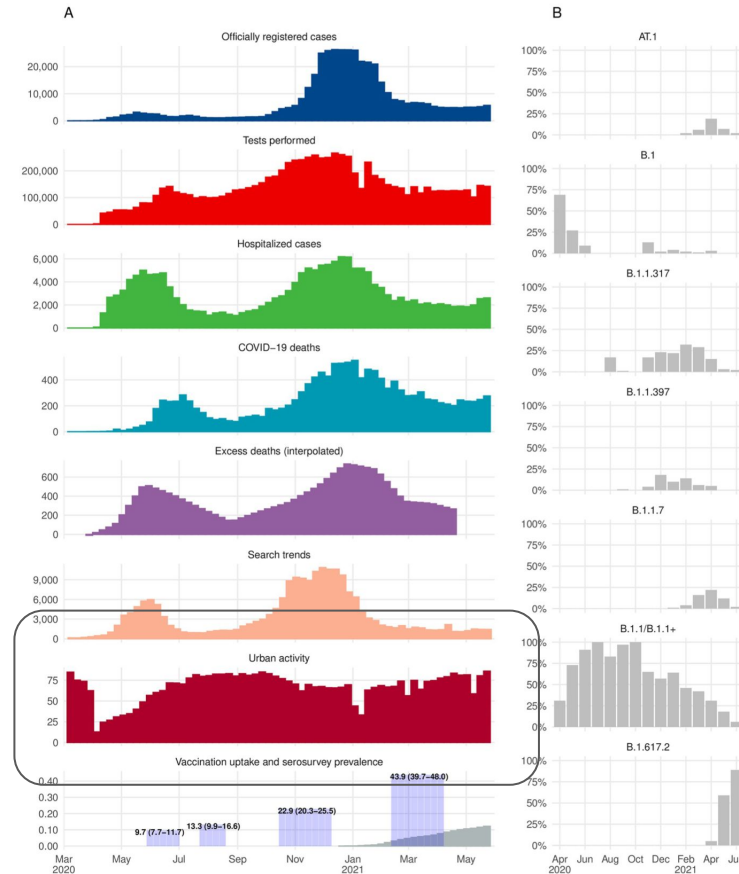


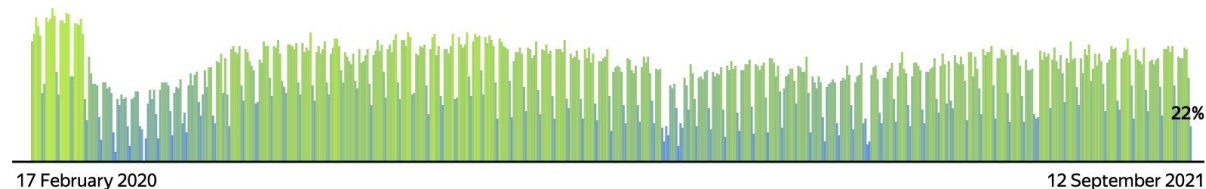
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Environment

Urban activity around the world

Level of activity in each city on a specific day compared to the busiest day in that city in February and early March of 2020.

Helsinki

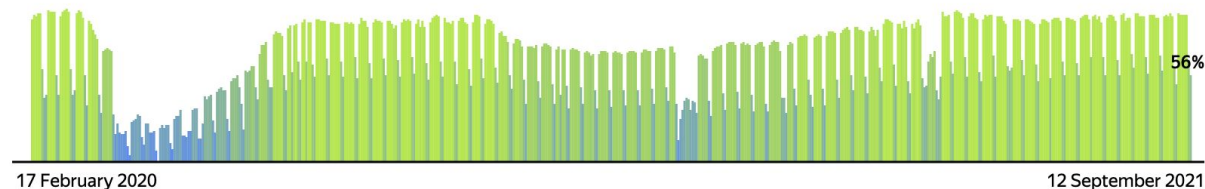


ACCORDING TO YANDEX, APPLE AND OTONOMO

Urban activity around the world

Level of activity in each city on a specific day compared to the busiest day in that city in February and early March of 2020.

Moscow



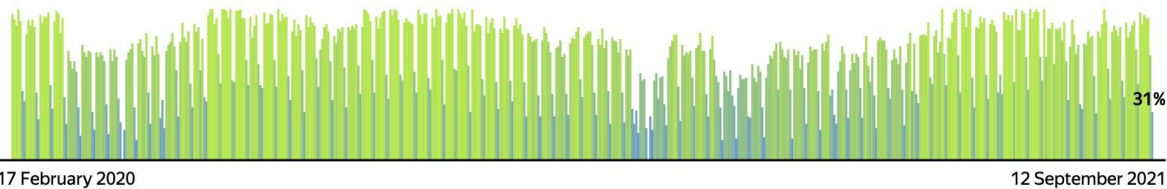
ACCORDING TO YANDEX, APPLE AND OTONOMO

Environment

Urban activity around the world

Level of activity in each city on a specific day compared to the busiest day in that city in February and early March of 2020.

Stockholm

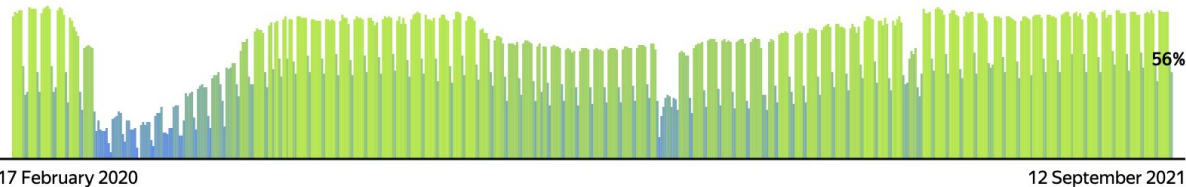


ACCORDING TO YANDEX, APPLE AND OTONOMO

Urban activity around the world

Level of activity in each city on a specific day compared to the busiest day in that city in February and early March of 2020.

Moscow



ACCORDING TO YANDEX, APPLE AND OTONOMO

Host: Management

Пандемия коронавируса, 18 янв, 06:01 | 👁 17 050 | Поделиться ➦

Россияне потратили более 64 млрд руб. на лекарства от COVID-19

Россияне в 2021 году потратили более 64 млрд руб. на лекарства от COVID-19

Больше всего граждане израсходовали на противовирусный препарат умифеновир — 16,8 млрд руб. Наибольшие траты понесли москвичи и жители Московской области — по 5 млрд руб., а также Краснодарского края — 3 млрд руб.

INAUGURAL ARTICLE



Structural basis of influenza virus fusion inhibition by the antiviral drug Arbidol

Rameshwar U. Kadam and Ian A. Wilson

[+ See all authors and affiliations](#)

PNAS January 10, 2017 114 (2) 206-214; first published December 21, 2016;
<https://doi.org/10.1073/pnas.1617020114>

Contributed by Ian A. Wilson, November 26, 2016 (sent for review October 18, 2016; reviewed by Robert M. Stroud and Jonathan W. Yewdell)

Article

Figures & SI

Info & Metrics

PDF

Significance

Influenza virus is an important human pathogen. The circulating strains of influenza virus are constantly mutating and are acquiring resistance to all approved drugs. Therefore, development of influenza therapeutics against novel targets is urgently required. The hemagglutinin envelope glycoprotein (HA) is a promising target for small-molecule design. However, Arbidol is the only available antiviral drug that targets the HA. The absence of structural information on drug-HA complexes has hindered further therapeutic development efforts against this viral pathogen. Here, we report crystal structures of Arbidol in complex with influenza HAs. This structural information advances our understanding of how small molecules, such as Arbidol, can function as influenza fusion inhibitors and can be used for development of broad-spectrum, small-molecule therapeutics.

**Арбидол -
перспективный
противовирусный
препарат, который
связывает
гликопротеин вирус и
даже что-то еще!**

**Арбидол -
перспективная
противовирусная
молекула!**



**Арбидол - самый
популярный в
России препарат
против COVID-19!**

**Арбидол -
перспективная
противовирусная
молекула!**



**Арбидол - эффективное
лекарство!**



**Арбидол - самый
популярный в
России препарат
против COVID-19!**

Арбидол -
перспективная
противовирусная
молекула!

~~Арбидол - эффективное
лекарство!~~

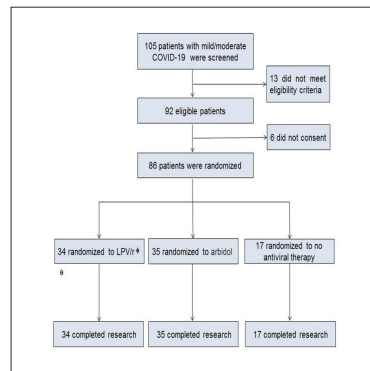
Арбидол - самый
популярный в
России препарат
против COVID-19!

Med

CellPress

Clinical Advances

Efficacy and Safety of Lopinavir/Ritonavir or Arbidol in Adult Patients with Mild/Moderate COVID-19: An Exploratory Randomized Controlled Trial



Yueping Li, Zhiwei Xie, Weyin Lin, ..., Fuchun Zhang, Xilong Deng, Linghua Li

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HIGHLIGHTS

Effective therapies against COVID-19 are urgently needed

Lopinavir/ritonavir and arbidol were tested in patients with mild/moderate COVID-19

Neither treatment shows significant advantage over supportive care

Several drugs are being tested against the novel coronavirus SARS-CoV-2, the pathogen responsible for the COVID-19 pandemic. Li et al. show that the drugs lopinavir/ritonavir and arbidol, which are currently used against HIV-1 and influenza, respectively, show little benefit over supportive care in patients with mild and moderate COVID-19.

Host: Vaccination

RESEARCH SUMMARY

Efficacy and Safety of mRNA-1273 SARS-CoV-2 Vaccine

L.R. Baden, et al. DOI: 10.1056/NEJMoa2035389

CLINICAL PROBLEM

The Covid-19 pandemic continues and expands. Additional data regarding vaccines to prevent symptomatic severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection are needed. The mRNA-1273 vaccine is a lipid-encapsulated mRNA vaccine encoding the prefusion stabilized spike protein of SARS-CoV-2.

CLINICAL TRIAL

A randomized, double-blind trial to evaluate the efficacy and safety of mRNA-1273.

30,420 participants ≥ 18 years old were assigned to receive either the vaccine or placebo in two intramuscular injections 28 days apart. Participants were followed for safety and the development of laboratory-confirmed, symptomatic Covid-19 over a median of 2 months after the second dose.

RESULTS

Safety:

Vaccine recipients had higher rates of local reactions (e.g., pain, erythema, swelling) and systemic reactions (e.g., headache, fatigue, myalgia) than placebo recipients. Most reactions were mild to moderate and resolved over 1–3 days.

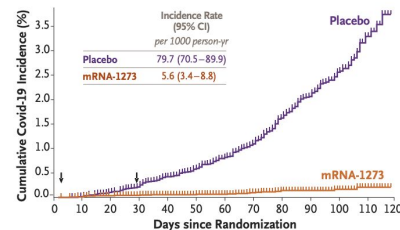
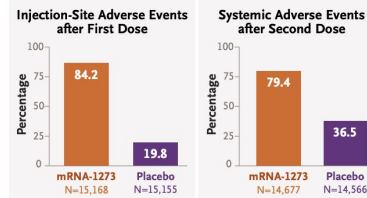
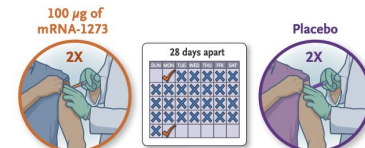
Efficacy:

The incidence of Covid-19 was lower among vaccine recipients than among placebo recipients as early as 14 days after the first dose. Protection in the vaccine group persisted for the period of follow-up.

LIMITATIONS AND REMAINING QUESTIONS

Further study is required to understand the following:

- Safety and efficacy over a longer period of time, in a larger population, and in pregnant women and children.
- Whether the vaccine protects against asymptomatic infection and transmission to unvaccinated persons.
- How to care for those who miss the second vaccine dose.



	mRNA-1273 Vaccine N=14,550	Placebo N=14,598
Symptomatic Covid-19	11	185
Severe Covid-19	0	30

Vaccine efficacy of 94.1% (95% CI, 89.3–96.8%; $P < 0.001$)

CONCLUSIONS

Two doses of a SARS-CoV-2 mRNA-based vaccine were safe and provided 94% efficacy against symptomatic Covid-19 in persons 18 or older.

Host: Vaccination

Safety and efficacy of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine: an interim analysis of a randomised controlled phase 3 trial in Russia



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Summary

Background A heterologous recombinant adenovirus (rAd)-based vaccine, Gam-COVID-Vac (Sputnik V), showed a good safety profile and induced strong humoral and cellular immune responses in participants in phase 1/2 clinical trials. Here, we report preliminary results on the efficacy and safety of Gam-COVID-Vac from the interim analysis of this phase 3 trial.

Methods We did a randomised, double-blind, placebo-controlled, phase 3 trial at 25 hospitals and polyclinics in Moscow, Russia. We included participants aged at least 18 years, with negative SARS-CoV-2 PCR and IgG and IgM tests, no infectious diseases in the 14 days before enrolment, and no other vaccinations in the 30 days before enrolment. Participants were randomly assigned (3:1) to receive vaccine or placebo, with stratification by age group. Investigators, participants, and all study staff were masked to group assignment. The vaccine was administered (0.5 mL/dose) intramuscularly in a prime-boost regimen: a 21-day interval between the first dose (rAd26) and the second dose (rAd5), both vectors carrying the gene for the full-length SARS-CoV-2 glycoprotein S. The primary outcome was the proportion of participants with PCR-confirmed COVID-19 from day 21 after receiving the first dose. All analyses excluded participants with protocol violations: the primary outcome was assessed in participants who had received two doses of vaccine or placebo, serious adverse events were assessed in all participants who had received at least one dose at the time of database lock, and rare adverse events were assessed in all participants who had received two doses and for whom all available data were verified in the case report form at the time of database lock. The trial is registered at ClinicalTrials.gov (NCT04530396).

Findings Between Sept 7 and Nov 24, 2020, 21977 adults were randomly assigned to the vaccine group (n=16501) or the placebo group (n=5476). 19866 received two doses of vaccine or placebo and were included in the primary outcome analysis. From 21 days after the first dose of vaccine (the day of dose 2), 16 (0.1%) of 14964 participants in the vaccine group and 62 (1.3%) of 4902 in the placebo group were confirmed to have COVID-19; vaccine efficacy was 91.6% (95% CI 85.6–95.2). Most reported adverse events were grade 1 (7485 [94.0%] of 7966 total events). 45 (0.3%) of 16427 participants in the vaccine group and 23 (0.4%) of 5435 participants in the placebo group had serious adverse events; none were considered associated with vaccination, with confirmation from the independent data monitoring committee. Four deaths were reported during the study (three [<0.1%] of 16427 participants in the vaccine group and one [<0.1%] of 5435 participants in the placebo group), none of which were considered related to the vaccine.

Interpretation This interim analysis of the phase 3 trial of Gam-COVID-Vac showed 91.6% efficacy against COVID-19 and was well tolerated in a large cohort.

Funding Moscow City Health Department, Russian Direct Investment Fund, and Sberbank.

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This online publication has been corrected. The corrected version first appeared at thelancet.com on February 18, 2021

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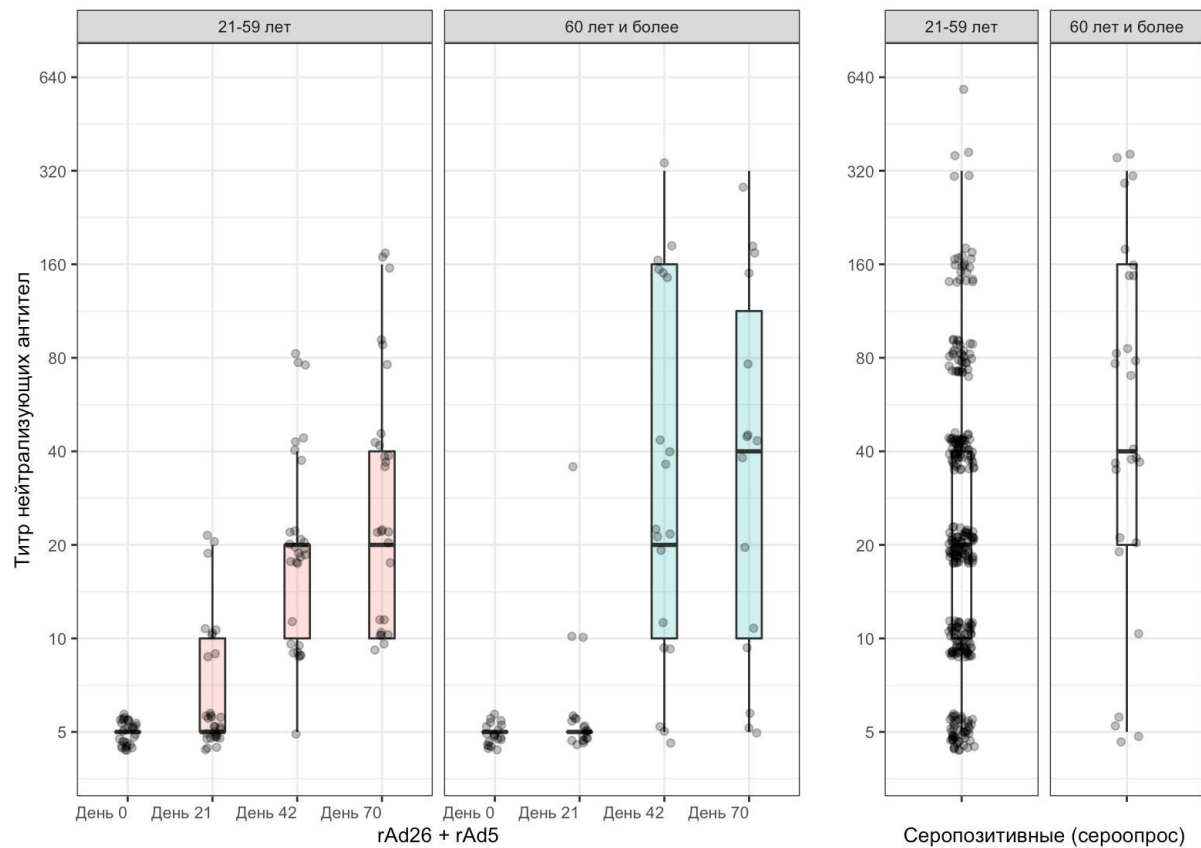
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**Сколько было
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исследований из России
опубликовано в журнале the Lancet
до 2021 года?**

Вакцинация Спутником



Нет рандомизированных исследований эффективности

ЭпиВакКорона

КовиВак

A.B. Ryzhikov et al.

Инфекция и иммунитет

the second immunization dose. No seroconversion was reported in the groups of volunteers vaccinated with a placebo. The peptide-based EpiVacCorona Vaccine has low reactogenicity and is a safe, immunogenic product. Clinical Trials Identifier: NCT04527575.

Key words: EpiVacCorona, peptide vaccine, clinical trials, COVID-19, coronavirus.

ПРОСТОЕ СЛЕПОЕ ПЛАЦЕБО-КОНТРОЛИРУЕМОЕ РАНДОМИЗИРОВАННОЕ ИССЛЕДОВАНИЕ БЕЗОПАСНОСТИ, РЕАКТОГЕННОСТИ И ИММУНОГЕННОСТИ ВАКЦИНЫ «ЭПИВАККОРОНА» ДЛЯ ПРОФИЛАКТИКИ COVID-19 НА ДОБРОВОЛЬЦАХ В ВОЗРАСТЕ 18–60 ЛЕТ (ФАЗА I–II)

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Резюме. Вакцинация населения — одна из наиболее эффективных мер противодействия пандемии, вызванной новой коронавирусной инфекцией. Поэтому ученые всего мира работают над созданием эффективных и безопасных вакцин. Мы разработали синтетическую пептидную вакцину «ЭпиВакКорона» против нового коронавируса SARS-CoV-2, которая представляет собой суспензию для внутримышечного введения, содержащую композицию химически синтезированных пептидных иммуногенов S-белка коронавируса SARS-CoV-2, конъюгированных с белком-носителем, и адсорбированных на гидроксиде алюминия. В настоящее время проводятся I–II фазы клинических испытаний вакцины, которые состоят из двух этапов: этап I — открытое исследование безопасности, реактогенности и иммунологической активности вакцины с участием 14 добровольцев в возрасте 18–30 лет, этап 2 — простое слепое сравнительное рандомизированное плацебо-контролируемое исследование с участием 86 добровольцев. В исследовании приняли участие добровольцы в возрасте 18–60 лет, вакцину вводили внутримышечно дважды с интервалом 21 день между инъекциями. Все местные реакции на введение вакцины были умеренными, например кратковременная боль в месте инъекции. Признаков развития местных или системных побочных реакций не было. Схема двухдозовой вакцинации вызвала выработку антител, специфичных к антигенам, из которых состоит вакцина, у 100% добровольцев. Сeroконверсия с титром нейтрализующих антител $\geq 1:20$ была зарегистрирована у 100% добровольцев через 21 день после второй дозы иммунизации. В группах добровольцев, вакцинированных плацебо, о сероконверсии не сообщалось. Вакцина «ЭпиВакКорона» на основе пептидов имеет низкую реактогенность, является иммуногенным и безопасным продуктом. Clinical Trials Identifier: NCT04527575.

Ключевые слова: ЭпиВакКорона, пептидная вакцина, клинические исследования, COVID-19, коронавирусы.

Introduction

Over the past two decades, coronaviruses have caused epidemic outbreaks of two respiratory diseases: Middle East Respiratory Syndrome and Severe Acute Respiratory Syndrome [3, 15]. In late 2019,

based on the following technological platforms: sub-unit, vector replicating, and vector non-replicating, RNA and DNA vaccines; inactivated, live attenuated, and virus-like particle-based vaccines [9].

We have developed EpiVacCorona Vaccine, containing chemically synthesized peptide immuno-

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Long-term humoral immunogenicity, safety and protective efficacy of inactivated vaccine against COVID-19 (CoviVac) in preclinical studies

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ABSTRACT

The unprecedented in recent history global COVID-19 pandemic urged the implementation of all existing vaccine platforms to ensure the availability of the vaccines against COVID-19 to every country in the world. Despite the multitude of high-quality papers describing clinical trials of different vaccine products, basic detailed data on general toxicity, reproductive toxicity, immunogenicity, protective efficacy and durability of immune response in animal models are scarce. Here, we developed a β -propiolactone-inactivated whole virion vaccine CoviVac and assessed its safety, protective efficacy, immunogenicity and stability of the immune response in rodents and non-human primates. The vaccine showed no signs of acute/chronic, reproductive, embryo- and fetotoxicity, or teratogenic effects, as well as no allergenic properties in studied animal species. The vaccine induced stable and robust humoral immune response both in form of specific anti-SARS-CoV-2 IgG and NAb in mice, Syrian hamsters, and common marmosets. The NAb levels did not decrease significantly over the course of one year. The course of two immunizations protected Syrian hamsters from severe pneumonia upon intranasal challenge with the live virus. Robustness of the vaccine manufacturing process was demonstrated as well. These data encouraged further evaluation of CoviVac in clinical trials.

Достаточно ли рандомизированных исследований для оценки эффективности?

Достаточно ли рандомизированных исследований для оценки эффективности?

RESEARCH SUMMARY

Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant

Lopez Bernal J et al. DOI: 10.1056/NEJMoa2108891

CLINICAL PROBLEM

The B.1.617.2 (delta) variant of SARS-CoV-2 became the dominant variant in India as of mid-April 2021, amid a Covid-19 surge there, and has spread rapidly around the world. The effectiveness of available vaccines in preventing symptomatic disease with this variant is unknown.

CLINICAL TRIAL

Design: A test-negative case-control study was conducted to estimate the effectiveness of the BNT162b2 (Pfizer-BioNTech) and ChAdOx1 nCoV-19 (AstraZeneca) vaccines against symptomatic disease from the delta variant of SARS-CoV-2.

Methods: Researchers examined data from symptomatic persons 16 years of age or older who underwent Covid-19 testing in England between October 2020 and May 2021. To estimate vaccine effectiveness, they assessed vaccination status in 4272 persons who tested positive for the delta variant and in 14,837 who tested positive for the B.1.1.7 (alpha) variant (the predominant strain in England at the time), as compared with test-negative controls.

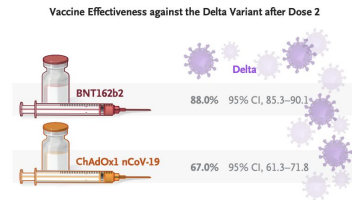
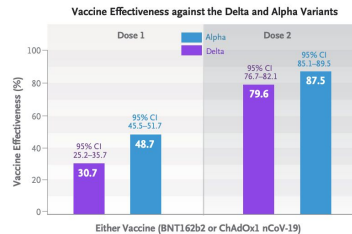
RESULTS

Effectiveness: After one dose of either vaccine, the estimated effectiveness was lower against delta than against alpha. After two doses, however, vaccine effectiveness was high, with only modest differences between the variants. The effectiveness of two doses against delta was lower with ChAdOx1 nCoV-19 than with BNT162b2.

LIMITATIONS AND REMAINING QUESTIONS

- How well do Covid-19 vaccines protect against severe disease, including hospitalization and death, from infection with the delta variant?

Links: Full Article | NEJM Quick Take | Editorial



CONCLUSIONS

Two doses of the BNT162b2 or ChAdOx1 nCoV-19 vaccine were highly effective against the delta variant of SARS-CoV-2, although slightly less so than against the alpha variant.

Russia's Sputnik V protects against severe COVID-19 from Delta variant, study shows

Two shots offer 81% protection from hospitalization and prevent lung injury, data from St. Petersburg suggest

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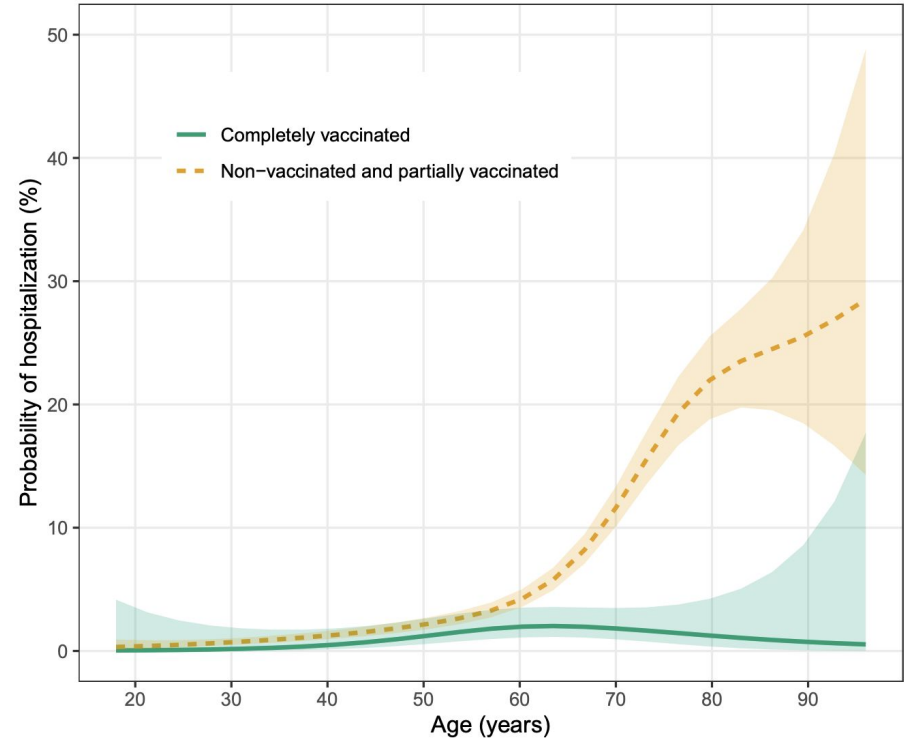
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Vaccine effectiveness against referral to hospital after SARS-CoV-2 infection in St. Petersburg, Russia, during the Delta variant surge: a test-negative case-control study

[Anton Barchuk](#) , [Mikhail Cherkashin](#), [Anna Bulina](#), [Natalia Berezina](#), [Tatyana Rakova](#), [Darya Kuplevatskaya](#), [Oksana Stanevich](#), [Dmitriy Skougarevskiy](#) & [Artemiy Okhotin](#)

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**Риски тяжелого течения у
вакцинированных меньше в пять раз!**

Но какая защита от инфекции?

И как там ЭпиВакКорона и КовиВак?

COVID-19 vaccines effectiveness against symptomatic SARS-CoV-2 during Delta variant surge: a preliminary assessment from a case-control study in St. Petersburg, Russia

Anton Barchuk , [Anna Bulina](#), [Mikhail Cherkashin](#), [Natalia Berezina](#), [Tatyana Rakova](#), [Darya Kuplevatskaya](#), [Oksana Stanevich](#), [Dmitriy Skougarevskiy](#) & [Artemiy Okhotin](#)

BMC Public Health 22, Article number: 1803 (2022) | [Cite this article](#)

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	Crude VE (95% CI)	VE adjusted for age and gender (95% CI)	VE adjusted for age, gender, and history of confirmed COVID-19 (95% CI)
Gam-COVID-Vac (2-dose Sputnik V)	45% (36–54)	50% (42–58)	58% (50–64)
Gam-COVID-Vac (1-dose Sputnik Light)	48% (29–62)	51% (32–64)	50% (30–64)
EpiVacCorona	-86% (-291–12)	-64% (-230–19)	-40% (-191–33)
CoviVac	32% (-6–56)	33% (-6–58)	38% (0–62)
Other	-11% (-112–42)	-17% (-113–36)	7% (-73–50)
Any vaccine: partial vaccination	23% (-32–55)	25% (-31–57)	27% (-31–60)

Расчет эффективности вакцинации в популяциях с большим количеством переболевших затруднен.

Расчет эффективности вакцинации против инфекции новым вариантом Омикрон еще более проблематичен.

Если бы в России были построены когорты для наблюдения за эффективностью и безопасностью вакцинации многие проблемы наблюдательных исследований были бы решены.

Table 2

Estimated unadjusted and adjusted effectiveness of five different vaccine types against SARS-CoV-2 infection and COVID-19-related death in the fully vaccinated study population ≥ 7 days after the second dose in Hungary

Vaccinated person			Vaccine effectiveness							
Vaccine	Age	n	SARS-CoV-2 infection			COVID-19-related mortality				
			Unadjusted	95% CI ^a	Adjusted	95% CI ^a	Unadjusted	95% CI ^a	Adjusted	95% CI ^a
Pfizer-BioNTech	16–24	67 149	86.6%	(83.4%–89.2%)	82.3%	(78.1%–85.7%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	25–34	144 278	88.4%	(86.8%–89.8%)	83.2%	(80.8%–85.2%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	35–44	208 085	89.8%	(88.7%–90.8%)	84.2%	(82.4%–85.8%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	45–54	231 593	90.3%	(89.4%–91.0%)	85.6%	(84.3%–86.9%)	89.1%	(77.1%–94.8%)	84.2%	(66.8%–92.5%)
	55–64	232 871	91.5%	(90.6%–92.4%)	85.0%	(83.4%–86.5%)	94.9%	(90.5%–97.3%)	92.7%	(86.5%–96.1%)
	65–74	310 079	94.4%	(93.7%–95.1%)	85.3%	(83.5%–86.9%)	95.8%	(93.8%–97.1%)	94.3%	(91.6%–96.1%)
	75–84	230 046	88.9%	(87.8%–89.8%)	82.1%	(80.4%–83.6%)	90.9%	(89.1%–92.5%)	91.3%	(89.6%–92.8%)
	85+	72 910	78.0%	(75.5%–80.2%)	74.3%	(71.4%–76.8%)	83.9%	(80.7%–86.6%)	87.1%	(84.5%–89.3%)
Total		1 497 011	90.6%	(90.2%–90.9%)	83.3%	(82.6%–83.9%)	74.3%	(71.0%–77.1%)	90.6%	(89.4%–91.7%)
Moderna	16–24	10 312	96.2%	(88.3%–98.8%)	80.5%	(39.4%–93.7%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	25–34	20 658	99.5%	(96.8%–99.9%)	97.0%	(78.6%–99.6%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	35–44	34 890	98.7%	(97.1%–99.4%)	90.6%	(79.1%–95.8%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	45–54	40 781	99.1%	(98.1%–99.6%)	93.6%	(86.7%–97.0%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	55–64	35 726	97.2%	(95.6%–98.2%)	84.5%	(75.7%–90.1%)	92.4%	(69.6%–98.1%)	80.3%	(20.9%–95.1%)
	65–74	39 118	98.1%	(96.9%–98.9%)	93.2%	(88.8%–95.8%)	95.1%	(88.3%–98.0%)	91.1%	(87.7%–96.3%)
	75–84	27 111	94.9%	(92.9%–96.3%)	88.9%	(84.5%–92.0%)	97.8%	(94.2%–99.2%)	97.0%	(92.0%–98.9%)
	85+	14 296	87.6%	(83.7%–90.5%)	84.1%	(79.0%–87.9%)	92.2%	(86.5%–95.5%)	92.5%	(87.0%–95.6%)
Total		222 892	96.9%	(96.4%–97.4%)	88.7%	(86.6%–90.4%)	83.0%	(74.6%–88.6%)	93.6%	(90.5%–95.7%)
Sputnik-V	16–24	55 632	97.0%	(94.9%–98.3%)	75.5%	(57.7%–85.8%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	25–34	94 808	97.8%	(96.8%–98.5%)	82.7%	(75.1%–88.0%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	35–44	167 038	98.0%	(97.5%–98.5%)	84.7%	(80.1%–88.1%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	45–54	194 601	98.2%	(97.8%–98.5%)	85.7%	(82.4%–88.3%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	55–64	166 499	96.6%	(96.0%–97.1%)	84.8%	(82.1%–87.0%)	98.6%	(95.5%–99.5%)	96.7%	(89.8%–98.9%)
	65–74	120 096	96.5%	(95.8%–97.0%)	87.8%	(85.4%–89.8%)	99.0%	(97.7%–99.6%)	98.2%	(95.7%–99.3%)
	75–84	20 056	95.1%	(92.7%–96.7%)	85.9%	(79.1%–90.5%)	97.3%	(92.9%–99.0%)	95.4%	(87.8%–98.3%)
	85+	1830	97.0%	(78.4%–99.6%)	90.9%	(35.7%–98.7%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
Total		820 560	97.1%	(96.8%–97.3%)	85.7%	(84.3%–86.9%)	98.0%	(96.4%–98.8%)	97.5%	(95.6%–98.6%)
AstraZeneca	16–24	8895	89.9%	(77.5%–95.5%)	68.5%	(29.9%–85.9%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	25–34	15 313	90.2%	(83.9%–94.0%)	77.2%	(62.8%–86.1%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	35–44	32 886	85.2%	(81.6%–88.1%)	68.6%	(60.8%–74.9%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	45–54	88 266	86.7%	(85.1%–88.1%)	73.5%	(70.3%–76.5%)	81.9%	(56.5%–92.5%)	74.3%	(38.0%–89.3%)
	55–64	79 206	83.2%	(81.1%–85.1%)	68.3%	(64.1%–72.0%)	93.3%	(83.9%–97.2%)	90.8%	(77.8%–96.2%)
	65–74	51 838	97.8%	(94.8%–99.1%)	72.2%	(33.2%–88.5%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	75–84	23 722	96.5%	(89.2%–98.9%)	64.8%	(–9.2%–88.7%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	85+	3912	90.7%	(34.1%–98.7%)	38.7%	(0%–91.4%)	81.3%	(–134%–91.4%)	38.3%	(–340%–91.4%)
Total		304 138	84.1%	(82.9%–85.3%)	71.5%	(69.2%–73.6%)	92.9%	(87.3%–96.1%)	88.3%	(78.7%–93.5%)
Sinopharm	16–24	65 720	97.4%	(93.7%–98.9%)	67.3%	(21.3%–86.4%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	25–34	91 946	98.5%	(96.7%–99.3%)	84.6%	(65.8%–93.1%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	35–44	104 018	95.6%	(93.5%–97.1%)	69.0%	(53.7%–79.3%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	45–54	80 960	95.8%	(94.0%–97.1%)	78.6%	(69.2%–85.2%)	100.0%	(NA–100.0%)	100.0%*	(NA–NA)
	55–64	126 028	85.6%	(84.2%–86.9%)	66.1%	(62.6%–69.3%)	92.5%	(86.8%–95.8%)	87.9%	(78.5%–93.1%)
	65–74	281 725	87.1%	(86.3%–87.8%)	71.1%	(69.0%–73.1%)	94.1%	(92.6%–95.2%)	91.1%	(88.9%–92.9%)
	75–84	130 323	82.2%	(80.6%–83.7%)	66.4%	(63.1%–69.4%)	90.0%	(87.8%–91.8%)	86.7%	(83.7%–89.1%)
	85+	14 745	69.8%	(62.1%–76.0%)	43.1%	(28.3%–54.9%)	75.7%	(64.7%–83.3%)	67.3%	(52.3%–77.6%)
Total		895 465	86.9%	(86.4%–87.5%)	68.7%	(67.2%–70.1%)	66.1%	(61.3%–70.3%)	87.8%	(86.1%–89.4%)

Сравнение вакцин // Венгрия

Pfizer-BioNTech - 83.3%
Moderna - 88.7%
Sputnik V - 85.7%
AstraZeneca - 71.5%
Sinopharm - 68.7%

Post-Omicron

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Gam-COVID-Vac, EpiVacCorona, and CoviVac effectiveness against lung injury during Delta and Omicron variant surges in St. Petersburg, Russia: a test-negative case-control study

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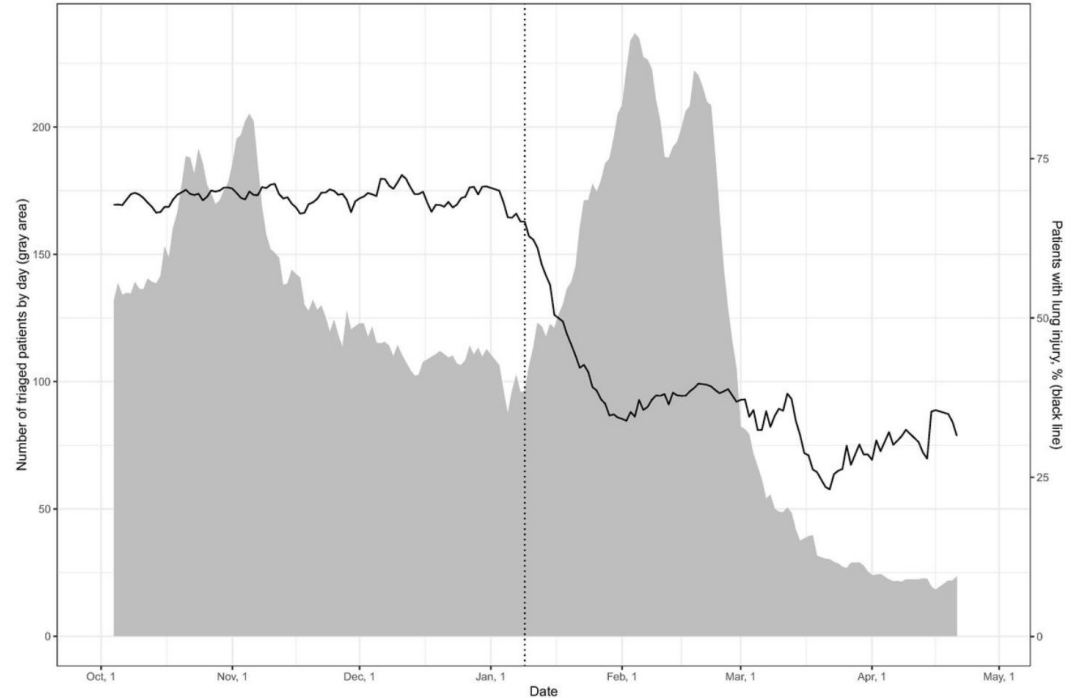
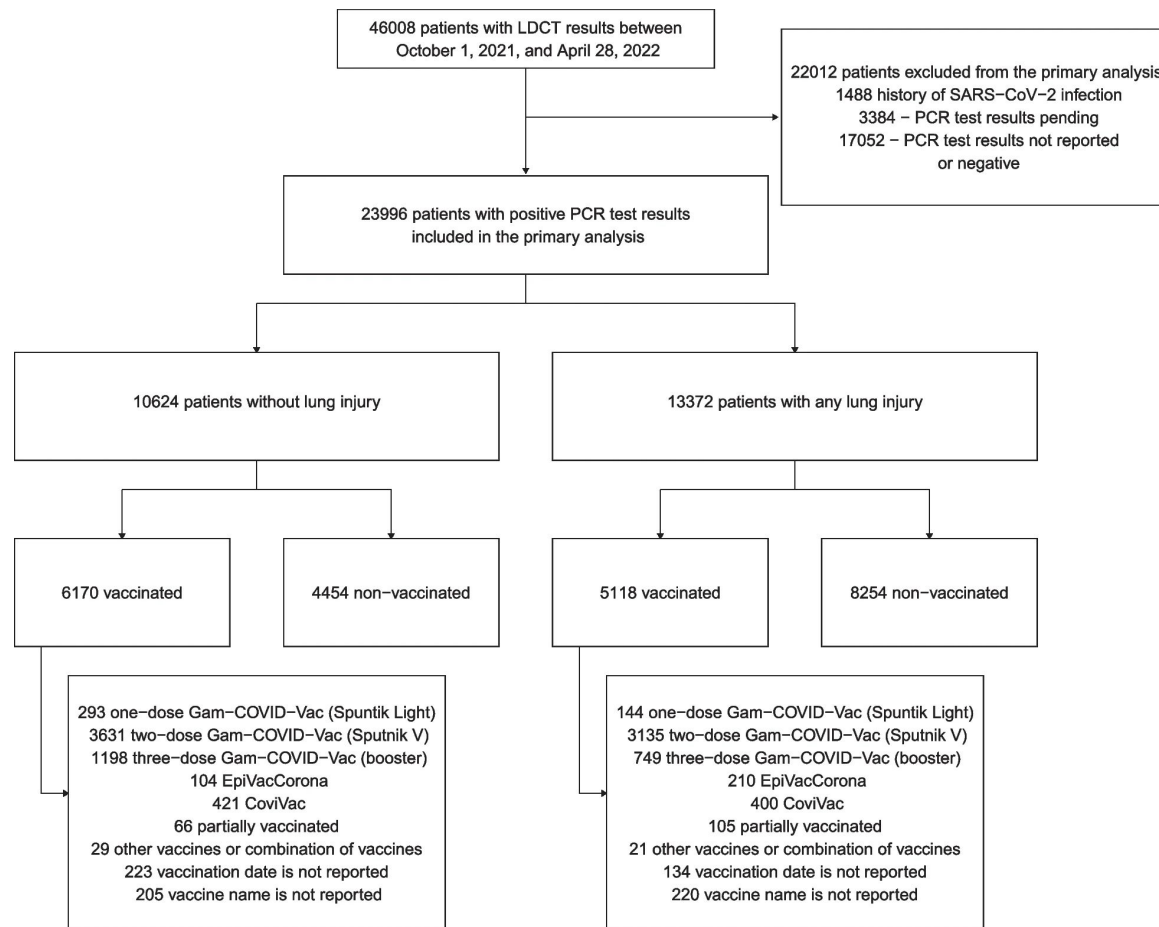


Figure 2

Patients dynamics and proportion of patients with any lung injury through the study period October 2021 - April 2022 (dashed vertical line marks the start of the Omicron surge).



Post-Omicron

Table 2 Effectiveness of vaccination against any and severe lung injury

	VE against any lung injury		Severe lung injury	
	Crude (95% confidence interval)	Adjusted for age, sex and triage center (95% confidence interval)	Crude (95% confidence interval)	Adjusted for age, sex and triage center (95% confidence interval)
One-dose Gam-COVID-Vac	73% (68 to 78)	74% (68 to 79)	94% (58 to 99)	94% (60 to 99)
Two-dose Gam-COVID-Vac	53% (51 to 56)	56% (54 to 59)	75% (66 to 82)	76% (67 to 82)
Three-dose Gam-COVID-Vac	66% (63 to 69)	71% (68 to 74)	84% (71 to 91)	87% (76 to 93)
EpiVacCorona	– 9% (– 38 to 14)	2% (– 27 to 24)	17% (– 106 to 66)	36% (– 63 to 75)
CoviVac	49% (41 to 56)	46% (37 to 53)	84% (56 to 94)	80% (45 to 92)

Post-Omicron

Table 3 Effectiveness of vaccination against any lung injury, according to age group, sex and study period

		One-dose Gam- COVID-Vac (Sputnik Light)	Two-dose Gam- COVID-Vac (Sputnik V)	Three-dose Gam- COVID-Vac (booster)	EpiVacCorona	CoviVac
Age (categories)	18–30	81% (50 to 92)	67% (58 to 73)	74% (60 to 83)	–60% (– 309 to 37)	28% (– 13 to 55)
	31–40	69% (48 to 82)	67% (61 to 71)	68% (58 to 76)	– 8% (– 97 to 41)	63% (48 to 74)
	41–50	70% (53 to 81)	56% (49 to 61)	65% (56 to 72)	– 36% (– 137 to 22)	34% (12 to 51)
	51–60	76% (64 to 84)	55% (48 to 61)	69% (61 to 75)	0% (– 72 to 42)	44% (25 to 57)
	61 +	78% (68 to 84)	50% (43 to 55)	74% (70 to 78)	33% (0 to 55)	57% (40 to 69)
Sex	Female	70% (62 to 77)	56% (53 to 60)	71% (67 to 75)	– 11% (– 53 to 20)	49% (39 to 57)
	Male	81% (72 to 87)	57% (52 to 61)	71% (65 to 76)	20% (– 20 to 47)	37% (19 to 52)
Period	Delta	57% (32 to 72)	59% (55 to 62)	57% (48 to 64)	– 35% (– 100 to 9)	41% (27 to 52)
	Omicron	54% (40 to 64)	38% (32 to 44)	57% (51 to 63)	5% (– 43 to 37)	30% (12 to 44)

Заключение

1. Да, активная фаза пандемии завершилась.
2. Длительность защиты?
3. Вакцинация людей с рисками снижения защиты - онкологические больные.
4. Новый вариант=новый инфекционный агент=новая пандемия