CADTH COVID-19 PANDEMIC

COVID-19 CADTH HEALTH TECHNOLOGY REVIEW

Ongoing Trials for Novel Vaccines in the Prevention of COVID-19

This report is current as of August 10, 2020.
To produce this report, CADTH used a modified approach to the selection of the evidence to meet decision-making needs during the COVID-19 pandemic. Care has been taken to ensure the information is accurate and complete, but it should be noted that international scientific evidence about COVID-19 is changing and growing rapidly.

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Questions or requests for information about this report can be directed to **requests@cadth.ca.**

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1.0	June 19, 2020	Information current as of June 10, 2020
2.0	June 26, 2020	Five trials added. Information current as of June 24, 2020
3.0	July 9, 2020	Three trials added. Information current as of July 8, 2020
4.0	July 23, 2020	Eight trials added. Information current as of July 22, 2020
5.0	August 11, 2020	One trial added. Information current as of August 10, 2020

About This Document

This report provides information on the ongoing phase II and phase III trials for novel vaccines in the prevention of COVID-19. It is important to note that this report is not a systematic review and does not include critical appraisal of studies. It is not intended to provide any recommendations.

In Canada, the National Advisory Committee on Immunization makes recommendations for the use of vaccines that are approved for use in humans and also identifies target groups for vaccination. Statements and publications by the National Advisory Committee on Immunization related to COVID-19 will be available at https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci.html.[1]

Background

Currently, there is no vaccine authorized for use to prevent COVID-19 outside of clinical trials. However, there is a growing number of vaccines at various stages of development to prevent COVID-19. As of July 31, 2020, WHO has identified 26 candidate vaccines that are currently in clinical evaluation (phase I, II, or III) and 139 candidate vaccines in pre-clinical evaluation for COVID-19.[2] This includes eight vaccine platforms: inactivated virus, live attenuated virus, replicating viral vector, non-replicating viral vector, ribonucleic acid (RNA), DNA, protein subunit, and virus-like particle.[2]

Vaccines prime the immune system to recognize the target virus in order to prevent it from replicating and causing infection.[3] Live, attenuated vaccines are weakened forms of the virus that can prompt an immune response without causing disease.[4] Examples of live attenuated vaccines include vaccines for measle, mumps and rubella,[5] and varicella-zoster virus.[6] Inactivated vaccines are killed versions of the virus that can prompt an immune response without causing infection.[7] Examples of inactivated vaccines include influenza vaccine[8] and hepatitis A vaccine.[9] Newer technologies such as RNA- and DNA-based platforms rely on providing the genetic coding for viral antigen proteins so that these proteins can be produced within the cells of the inoculated individuals.[10] A major advantage of this approach is the relative speed of vaccine production, as it relies on synthetic processes rather than large-scale culture or fermentation processes.[11]

DNA and RNA can be introduced into host cells by physical or biochemical means. A variation of this approach uses non-replicating viral vectors — weakened, genetically altered versions of a “carrier” virus such as adenovirus (a common cold virus) used to introduce and express genetic coding for specific viral proteins (e.g., spike glycoprotein found on severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2) in the host.[12,13] Non-replicating viral vectors, together with other platforms such as replicating viral vector and protein subunit, have the advantage of high scalability.[11] In addition, non-replicating and replicating viral vectors and live attenuated vaccines only require a single dose, whereas other platforms involve vaccines that require multiple doses to develop adequate immunity.[11]

However, additional testing for safety is often required for live attenuated vaccines.[4] Other characteristics that may differ between these vaccine platforms include the impact on humoral and cellular immune pathways, the durability of immunity, and vaccine stability in storage.[14]

The purpose of this report is to provide information on the ongoing clinical trials for novel vaccines in the prevention of COVID-19 that are in phase II and III. Ongoing trials for Bacille Calmette-Guérin (BCG) vaccine, plasma products, and drugs for COVID-19 are reviewed in separate CADTH reports.[15]

Objective

To describe the trial characteristics and estimated primary completion dates of the ongoing phase II and phase III studies evaluating novel vaccines for the prevention of COVID-19.

Selection Criteria and Methods

The trials were identified from ClinicalTrials.gov,[16] Health Canada's Clinical Trials Database,[17] and the WHO International Clinical Trials Registry Platform[18] using the inclusion criteria presented in Table 1. In addition, grey literature relating to novel vaccines and COVID-19 was identified by searching relevant websites from *the Grey Matters: A Practical Tool For Searching Health-Related Grey Literature* checklist[19] and CADTH COVID-19 Grey Literature Resources,[20] which include the websites of regulatory agencies, health technology assessment agencies, and clinical guideline repositories. Google was used to search for additional internet-based materials.

Table 1: Selection Criteria

Population	Healthy people or people at risk of Sars-CoV2 infection (COVID-19)
Intervention	Prophylactic vaccines targeting Sars-CoV2
Comparator	No restriction
Outcomes	No restriction
Study design	Phase II or III (including phase I/II and phase II/III)

SARS-CoV2 = severe acute respiratory syndrome coronavirus 2.

Exclusion Criteria

Trials investigating BCG vaccines, BCG-based vaccines, and other repurposed vaccines (e.g., measles-mumps-rubella) were excluded. Therapeutic vaccines were excluded. Phase I trials and pre-clinical studies were excluded.

The results are organized according to the phase of clinical development and in order of estimated primary completion dates (earlier first).

Results

As of August 10, 2020, a total of 34 trials met the inclusion and exclusion criteria as follows: 23 phase I/II trials, four phase II trials, one phase II/III trial, one phase I/II/III trial, and five phase III trials (Table 2). The estimated enrolment for these trials ranges from 30 patients to 60,000 patients. All of the trials are being conducted in adults, with five trials including children. Twelve phase I/II trials are expected to reach their primary completion dates by the end of 2020. One phase I/II trial is being conducted in Canada.

Other resources from the grey literature search are presented in Appendix 1, Table 3. These resources did not meet the inclusion criteria.

Limitations

The information provided in Table 2 relies on the information posted on ClinicalTrials.gov, the WHO International Clinical Trials Registry Platform, and Health Canada's Clinical Trials Database and may be subject to reporting errors in the posted study records.[21] Furthermore, reporting of protocol amendments to the posted study records may be delayed. Finally, not all trials are posted in the selected trial registries and, as such, all ongoing trials may not be listed.

Summary

A total of 34 trials investigating novel vaccines for COVID-19 met the inclusion criteria. Twelve trials are expected to reach their primary completion dates by December 31, 2020. One trial is being conducted in Canada.

Table 2: Ongoing Trials of Novel Vaccines for the Prevention of COVID-19 (August 10, 2020)

Vaccine (platform) sponsor	Title of trial	Study design, estimated enrolment, location	Estimated primary completion date[a]	Population	Trial registry identifier, other study ID numbers	Study status
Phase III or Phase II/III or Phase I/II/III						
BNT-162 vaccine (RNA) BioNTech SE / Pfizer	A Phase I/II/III, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-CoV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Adults	Phase I/II/III RCT, DB, PC, MC N = 29,481 US, Argentina, Brazil	April 16, 2021	Healthy adults 18 to 85 years of age	NCT04368728 EudraCT Number 2020-002641-42	Recruiting
Inactivated SARs-CoV-2 vaccine (Vero cells) China National Biotec Group Co. Ltd.	Randomized, Double Blind, Parallel Placebo Controlled, Phase III Clinical Trial to Evaluate the Safety and Protective Efficacy of Inactivated SARS-CoV-2 Vaccine in Healthy Population Aged 18 Years and above	Phase III RCT, DB, PC N = 1,500 United Arab Emirates	July 15, 2021 (end of study)	Healthy adults aged 18 years and older	ChiCTR2000034780	Recruiting
ChAdOx1 nCoV-19 vaccine (Non-replicating viral vector) University of Oxford	A Phase 2/3 Study to Determine the Efficacy, Safety and Immunogenicity of the Candidate Coronavirus Disease (COVID-19) Vaccine ChAdOx1 nCoV-19	Phase II/III RCT, MC, single-blind N = 10,260 UK	August 2021	Healthy subjects aged 5 years and older	NCT04400838 EudraCT Number: 2020-001228-32 ISRCTN90906759 COV002	Recruiting

Vaccine (platform) sponsor	Title of trial	Study design, estimated enrolment, location	Estimated primary completion date[a]	Population	Trial registry identifier, other study ID numbers	Study status
Adsorbed COVID-19 (inactivated) vaccine Sinovac Life Sciences Co., Ltd.	Double-Blind, Randomized, Placebo-Controlled Phase III Clinical Trial to Evaluate Efficacy and Safety in Healthcare Professionals of the Adsorbed COVID-19 (Inactivated) Vaccine Manufactured by Sinovac	Phase III RCT, DB, PC, MC N = 8,870 Brazil	September 2021	Health care professionals working in specialized COVID-19 health care facilities; aged 18 and older	NCT04456595 COV-02-IB	Recruiting
ChAdOx1 nCoV-19 vaccine (Non-replicating viral vector) University of Oxford	A Phase III Randomized Controlled Trial to Determine Safety, Efficacy, and Immunogenicity of the Non-replicating ChAdOx1 nCoV-19 Vaccine	Phase III RCT, single-blind N = 2,000 Brazil	October 31, 2021 (overall trial end date)	Healthy adults aged 18- to 55-years old; upper age can be extended upon availability of additional safety data in older population	ISRCTN89951424 COV003	Recruiting
mRNA-1273 vaccine Moderna TX, Inc; Biomedical Advanced Research and Development Authority; National Institute of Allergy and Infectious Diseases (NIAID)	A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older	Phase III RCT, DB, PC, MC N = 30,000 US	October 27, 2022	Adults 18 years of age or older who are at high risk of SARS-CoV-2 infection	NCT04470427 mRNA-1273-P301	Recruiting

Vaccine (platform) sponsor	Title of trial	Study design, estimated enrolment, location	Estimated primary completion date[a]	Population	Trial registry identifier, other study ID numbers	Study status
Ad26.COV2.S vaccine Janssen Vaccines & Prevention B.V	A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older (ENSEMBLE)	Phase III RCT, DB, PC, MC N = 60,000 US, Brazil, Chile, Colombia, Mexico, Peru, Philippines, South Africa, Ukraine	March 10, 2023	Healthy adults 18 years of age or older	NCT04505722 CR108876	Not yet recruiting
Phase II or Phase I/II						
Inactivated SAR-CoV-2 vaccine (Inactivated plus alum) Sinovac Research and Development Co., Ltd.	A Randomized, Double-Blinded, Placebo-Controlled, Phase I/II Clinical Trial, to Evaluate the Safety and Immunogenicity of the SARS-CoV-2 Inactivated Vaccine in Healthy Adults Aged 18 to 59 Years	Phase I/II RCT, DB, PC N = 744 China	July 10, 2020 (actual primary completion date)	Healthy adults 18 to 59 years old	NCT04352608 PRO-nCOV-1001	Active, not recruiting
Gam-COVID-Vac (Non-replicating viral vector) Gamaleya Research Institute of Epidemiology and Microbiology, Health Ministry of the Russian Federation	An Open Study of the Safety, Tolerability and Immunogenicity of the Drug "Gam-COVID-Vac" a Solution for Intramuscular Injection With the Participation of Healthy Volunteers	Phase I/II, non-randomized, OL N = 38 Russia	August 5, 2020	Healthy adults aged 18 to 60 years old	NCT04436471 02-Gam-COVID-Vac-2020	Active, not recruiting

Vaccine (platform) sponsor	Title of trial	Study design, estimated enrolment, location	Estimated primary completion date[a]	Population	Trial registry identifier, other study ID numbers	Study status
Gam-COVID-Vac Lyo (Non-replicating viral vector) Gamaleya Research Institute of Epidemiology and Microbiology, Health Ministry of the Russian Federation	An Open Study of the Safety, Tolerability and Immunogenicity of the Drug "Gam-COVID-Vac Lyo" Lyophilizate for the Preparation of a Solution for Intramuscular Injection With the Participation of Healthy Volunteers	Phase I/II, non-randomized, OL N = 38 Russia	August 5, 2020	Healthy adults aged 18 to 60 years old	NCT04437875 03-Gam-COVID-Vac Lyo-2020	Active, not recruiting
BNT-162 vaccine (RNA) BioNTech RNA Pharmaceuticals GmbH	A Multi-site, Phase I/II, 2-Part, Dose-Escalation Trial Investigating the Safety and Immunogenicity of Four Prophylactic SARS-CoV-2 RNA Vaccines Against COVID-2019 Using Different Dosing Regimens in Healthy Adults	Phase I/II Non-randomized, OL N = 200 Germany	August 2020	Healthy adults 18 to 55 years old	NCT04380701 EudraCT Number: 2020-001038-36 BNT162-01	Recruiting
Inactivated SARS-CoV-2 vaccine (Inactivated plus alum) Sinovac Research and Development Co., Ltd.	A Randomized, Double-Blinded, Placebo-Controlled, Phase I/II Clinical Trial, to Evaluate the Safety and Immunogenicity of the SARS-CoV-2 Inactivated Vaccine (Vero Cell) in Healthy Population Aged ≥60 Years	Phase I/II RCT, DB, PC N = 422 China	August 30, 2020	Healthy adults aged 60 years and older	NCT04383574 PRO-nCOV-1002	Active, not recruiting

Vaccine (platform) sponsor	Title of trial	Study design, estimated enrolment, location	Estimated primary completion date[a]	Population	Trial registry identifier, other study ID numbers	Study status
Inactivated SARS-CoV-2 Vaccine Chinese Academy of Medical Sciences	A Randomized, Double-Blind, Placebo-Controlled, Phase Ia/IIa Trial of an Inactivated SARS-CoV-2 Vaccine in Healthy People Aged 18 to 59 Years	Phase Ia/IIa RCT, DB, PC N = 942 China	September 2020	Healthy adults aged 18 to 59 years	NCT04412538	Recruiting
DNA vaccine, AG0301-COVID19 AnGes, Inc.	A Non-randomized, Open-label, Non-controlled Phase I/II Study to Assess Safety and Immunogenicity of Two Doses of Intramuscular AG0301-COVID19 (1mg/2mg) in Healthy Adults	Phase I/II Non-randomized, OL, uncontrolled N = 30 Japan	September 26, 2020	Healthy adults aged 20 to 65 years	NCT04463472 AG0301-COVID19-JN-01	Recruiting
ChAdOx1 nCoV-19 (Non-replicating viral vector) University of Witwatersrand, South Africa University of Oxford	An Adaptive Phase I/II Randomized Placebo-controlled Trial to Determine Safety, Immunogenicity and Efficacy of Non-replicating ChAdOx1 SARS-CoV-2 Vaccine in South African Adults Living Without HIV; and Safety and Immunogenicity in Adults Living With HIV	Phase I/II RCT, DB, PC, MC N = 2,000 South Africa	October 2020	Healthy adults aged 18 to 65 years without HIV infection and those with HIV infection	NCT04444674 ChAdOx1 nCoV-19_ZA_phI/II	Recruiting

Vaccine (platform) sponsor	Title of trial	Study design, estimated enrolment, location	Estimated primary completion date[a]	Population	Trial registry identifier, other study ID numbers	Study status
Inactivated SARS-CoV-2 vaccine Chinese Academy of Medical Sciences	A Randomized, Double-Blind, Placebo-Controlled, Phase Ib/IIb Trial of an Inactivated SARS-CoV-2 Vaccine in Healthy People Aged ⩾60 Years	Phase Ib/IIb RCT, DB, PC N = 471 China	November 2020	Healthy adults aged 60 years and older	NCT04470609 20200402	Enrolling by invitation
AV-COVID-19 AIVITA Biomedical, Inc.	Adaptive Phase IB-II Randomized Clinical Trial Of Preventive Vaccine Consisting Of Autologous Dendritic Cells Loaded With Antigens From Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2), With Or Without GM-CSF, In Subjects Negative For COVID-19 Infection And Anti-SARS-CoV-2 Antibodies	Phase IB/II Randomized, DB N = 180 US	December 2020	Healthy adults aged 18 years and older	NCT04386252 CL-COV-P01-US	Not yet recruiting
ARCT-021 (RNA) Arcturus Therapeutics, Inc.	A Phase 1/2 Randomised, Double Blinded, Placebo Controlled, Ascending Dose Study to Assess the Safety, Tolerability, and Immunogenicity of ARCT-021 in Healthy Adult Subjects	Phase I/II RCT, DB, PC N = 85 Singapore	December 2020	Healthy adults aged 21 years to 80 years of age	NCT04480957 ARCT-021-01	Not yet recruiting

Vaccine (platform) sponsor	Title of trial	Study design, estimated enrolment, location	Estimated primary completion date[a]	Population	Trial registry identifier, other study ID numbers	Study status
SARS-CoV-2 rS nanoparticle vaccine with or without Matrix-M adjuvant (Protein Subunit) Novavax	A 2-Part, Phase 1/2, Randomized, Observer-Blinded Study To Evaluate The Safety And Immunogenicity Of A SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With Or Without MATRIX-M™ Adjuvant In Healthy Subjects	Phase I/II RCT, DB, PC, MC N = 131 Australia	December 31, 2020	Phase I: Healthy adults 18 to 59 years of age, inclusive	NCT04368988 2019nCoV-101	Recruiting
KBP-COVID-19 vaccine (Protein subunit) Kentucky BioProcessing, Inc.	A Phase I/II, First-in-human, Observer-blinded, Randomized, Placebo-controlled, Parallel Group Study to Evaluate the Safety and Immunogenicity of KBP-COVID-19 Vaccine in Healthy Seronegative Adults Aged 18-49 and 50-70	Phase I/II RCT, DB, PC N = 180 Location: NR	January 25, 2021	Healthy adults aged 18 to 70 years old	NCT04473690 KBP-201	Not yet recruiting
Ad5-nCoV (Non-replicating viral vector) Institute of Biotechnology, Academy of Military Medical Sciences, PLA of China	A Randomized, Double-blind, Placebo-controlled Phase II Clinical Trial to Evaluate the Safety and Immunogenicity of the Recombinant Novel Coronavirus Vaccine (Adenovirus Vector) in Healthy Adults Aged Above 18 Years	Phase II RCT, DB, PC N = 508 China	January 31, 2021	Healthy adults 18 to 60 years old	NCT04341389 JSVCT089	Active, not recruiting Published results (July 20, 2020)

Vaccine (platform) sponsor	Title of trial	Study design, estimated enrolment, location	Estimated primary completion date[a]	Population	Trial registry identifier, other study ID numbers	Study status
Recombinant novel coronavirus vaccine (adenovirus vector) (Non-replicating viral vector) Jiangsu Provincial Center for Disease Control and Prevention	A Randomized, Double-blinded, Placebo-controlled Phase II Clinical Trial for Recombinant Novel Coronavirus (2019-nCOV) Vaccine (Adenovirus Vector) in Healthy Adults Aged Above 18 Years	Phase II RCT, DB, PC N = 500 China	January 31, 2021 (end of study)	Healthy adults aged 18 years and older	ChiCTR2000031781	Not yet recruiting
GX-19, DNA vaccine expressing SARS-CoV-2 S-protein antigen (DNA) Genexine, Inc.	A Phase 1/2a, Multi-center, Randomized, Double-blind, Placebo-controlled Study to Investigate the Safety, Tolerability, and Immunogenicity of GX-19, a COVID-19 Preventive DNA Vaccine in Healthy Subjects	Phase I/IIa RCT, DB, PC N = 210 South Korea	March 17, 2021	Healthy adults aged 18 to 50 years old	NCT04445389 GX-19-HV-001	Recruiting
mRNA-1273 vaccine (RNA) ModernaTX, Inc.	A Phase 2a, Randomized, Observer-Blind, Placebo Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 SARS-COV-2 Vaccine in Adults Aged 18 Years and Older	Phase IIa RCT, DB, PC, MC N = 600 US	March 2021	Healthy adults aged 18 years and older	NCT04405076 mRNA-1273-P201	Active, not recruiting

Vaccine (platform) sponsor	Title of trial	Study design, estimated enrolment, location	Estimated primary completion date[a]	Population	Trial registry identifier, other study ID numbers	Study status
ChAdOx1 nCoV-19 (non-replicating viral vector) University of Oxford	A Phase I/II Study to Determine Efficacy, Safety and Immunogenicity of the Candidate Coronavirus Disease (COVID-19) Vaccine ChAdOx1 nCoV-19 in UK Healthy Adult Volunteers	Phase I/II RCT, MC, single-blind N = 1,090 UK	May 2021	Healthy adults 18 to 55 years old	NCT04324606 EudraCT Number: 2020-001072-15 ISRCTN15281137 (COV001)	Active, not recruiting Published results (July 20, 2020)
Whole-virion inactivated SARS-CoV-2 vaccine (BBV152) Bharat Biotech International Limited	An Adaptive Phase 1, Followed by Phase 2 Randomized, Double-blind, Multicenter Study to Evaluate the Safety, Reactogenicity, Tolerability, and Immunogenicity of the BBV152 in Healthy Volunteers	Phase I/II RCT, DB, PC, MC N = 1,125 India	June 30, 2021	Subjects aged 12 years to 65 years old	NCT04471519 BBIL/BBV152-A/2020 CTRI/2020/07/026300	Recruiting
SARS-CoV-2 vaccine, Ad26.COVS1, recombinant Janssen Vaccine & Prevention B.V.	A Randomized, Double-Blind, Placebo-Controlled Phase 1/2a Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Ad26COVS1 in Adults Aged 18 to 55 Years Inclusive and Adults Aged 65 Years and Older	Phase I/IIa RCT, DB, PC, MC N = 1,045 US, Belgium	Sept 15, 2021	Healthy adults aged 18 years and older	NCT04436276 EudraCT Number 2020-001483-28	Not yet recruiting

Vaccine (platform) sponsor	Title of trial	Study design, estimated enrolment, location	Estimated primary completion date[a]	Population	Trial registry identifier, other study ID numbers	Study status
Recombinant novel coronavirus vaccine (CHO cell) (Protein subunit) Anhui Zhifei Longcom Biologic Pharmacy Co., Ltd.	A Randomized, Blinded, Placebo-Controlled Trial to Evaluate the Immunogenicity and Safety of a Recombinant New Coronavirus Vaccine (CHO Cell) With Different Doses and Different Immunization Procedures in Healthy People Aged 18 to 59 Years	Phase II RCT, DB, PC N = 900 China	Sept 15, 2021	Healthy adults aged 18 years to 59 years of age	NCT04466085 NCV-II-healthy	Recruiting
Inactivated novel coronavirus pneumonia vaccine (vero cells) (Inactivated) Henan Provincial Center for Disease Control and Prevention	Evaluation of the Safety and Immunogenicity of Inactivated Novel Coronavirus Pneumonia (COVID-19) Vaccine (Vero cells) in Healthy Population Aged 6 Years and Above: A Randomized, Double-Blind, Placebo Parallel-Controlled Phase I/II Clinical Trial	Phase I/II RCT, DB, PC N = 1,456 China	November 10, 2021 (end of study)	Healthy subjects aged 6 years and older	ChiCTR2000031809	Not yet recruiting
Inactivated SARS-CoV-2 vaccine (vero cells) (inactivated) Henan Provincial Center for Disease Control and Prevention	Evaluation of the Safety and Immunogenicity of Inactivated Novel Coronavirus (2019-CoV) Vaccine (Vero Cells) in Healthy Population Aged 3 Years and Above: A Randomized, Double-Blind, Placebo Parallel-Controlled Phase I/II Clinical Trial	Phase I/II RCT, DB, PC N = 2,128 China	November 28, 2021 (end of study)	Healthy subjects aged 3 years and older	ChiCTR2000032459	Recruiting

Vaccine (platform) sponsor	Title of trial	Study design, estimated enrolment, location	Estimated primary completion date[a]	Population	Trial registry identifier, other study ID numbers	Study status
AD5-nCoV (non-replicating viral vector) CanSino Biologics Inc.	A Randomized, Observer-Blind, Dose-escalation Phase I/II Clinical Trial of Ad5-nCoV Vaccine in Healthy Adults From 18 to < 85 Years of Age in Canada	Phase I/II RCT, DB, PC N = 696 Canada	December 20, 2021	Healthy adults 18 to < 55 and 65 to < 85 years old	NCT04398147 Health Canada: AD5-nCOV-2020003	Not yet recruiting
INO-4800 (DNA plasmid vaccine with electroporation) Inovio Pharmaceuticals/ International Vaccine Institute	A Phase I/IIa, Dose-Ranging Trial to Evaluate Safety, Tolerability and Immunogenicity of INO-4800, a Prophylactic Vaccine Against SARS-CoV-2, Administered Intradermally Followed by Electroporation in Healthy Volunteers	Phase I/IIa Part B: RCT, DB, PC N = 160 Location: NR	February 22, 2022	Healthy adults aged 19 to 64 years old (Part B)	NCT04447781 IVI COVID19-001	Not yet recruiting
ChAdOx1 nCoV-19 vaccine (non-replicating viral vector) University of Oxford	A Phase Ib/II Single-Blinded, Randomised, Controlled Study to Determine Safety, Immunogenicity and Efficacy of the Candidate Coronavirus Disease (COVID-19) Vaccine ChAdOx1 nCoV-19 in Adults in Kenya	Phase Ib/II RCT, single-blind N = 400 Kenya	May 31, 2022 (Anticipated date of last follow-up)	Healthy adults aged 18 to 55 years for Phase Ib and 18 years or older for Phase II	PACTR202005681895696	Not yet recruiting

Vaccine (platform) sponsor	Title of trial	Study design, estimated enrolment, location	Estimated primary completion date[a]	Population	Trial registry identifier, other study ID numbers	Study status
nCov vaccine (DNA) Cadila Healthcare Ltd.	A Prospective, Randomized, Adaptive, Phase I/II Clinical Study to Evaluate the Safety and Immunogenicity of Novel Corona Virus -2019-nCov Vaccine Candidate of M/s Cadila Healthcare Limited by Intradermal Route in Healthy Subjects	Phase I/II RCT, outcome-assessor blinded, PC, MC N = 1,048 India	NR	Healthy subjects aged 18 to 55 years (phase I) and aged 12 years of age and older (phase II)	CTRI/2020/07/026352 NCOV 1002	Open to recruitment

Ad5-nCOV = adenovirus type 5 vector; DB = double blind; MC = multi-centre; NR = not reported; OL = open label; PC = placebo controlled; RCT = randomized controlled trial; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.

[a] The estimated date on which the data collection will be completed for all the primary outcome measures, unless otherwise indicated.

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Appendix 1: Other Resources

Table 3: Other Resources Regarding Novel Vaccines for COVID-19

Organization, title of resource (date)	Brief description or statement
Resources from Canada	
Government of Canada Government of Canada announces major steps in treating and preventing COVID-19 through vaccines and therapies[22] (August 5, 2020)	The Government of Canada announces it has entered into two agreements to secure a future supply of COVID-19 vaccines: BNT162 mRNA-based vaccine candidate (Pfizer) and mRNA-1273 vaccine candidate (Moderna). While all potential vaccine candidates will require Health Canada regulatory approval before they are available to Canadians, this move establishes a guaranteed supply of millions of doses. Other negotiations, investments, and procurement plans are described.
Government of Canada Government of Canada's research response to COVID-19 — Vaccines[23] (April 23, 2020)	The Government of Canada states that, "At this time, there is no vaccine authorized to protect against COVID-19. Nevertheless, early stage clinical trials for COVID-19 vaccines have already begun around the world, and Health Canada is working with vaccine developers and manufacturers to help expedite the development and availability of vaccines to prevent COVID-19. In Canada, current efforts are focused to advance projects that are already underway by university researchers and others to respond to COVID-19, and to build Canadian capacity to produce potential vaccines." Recently announced investments are provided in more detail.
Government of Canada Research priorities for COVID-19 vaccines to support public health decisions[24] (July 15, 2020)	Guidance is provided by the National Advisory Committee on Immunization (NACI) on considerations for early phase and late phase clinical trials investigating COVID-19 vaccines. Recommendations include priority populations for inclusion in clinical trials and considerations involving ethics, equity and feasibility, and health economics.
Government of Canada Drugs and vaccines for COVID-19: List of authorized clinical trials[25] (July 31, 2020)	The Government of Canada provides a list of authorized clinical trials for COVID-19 drugs, including vaccines that are currently underway in Canada. This list is updated by the Government of Canada as new trials are authorized by Health Canada.
Government of Canada Drugs and vaccines for COVID-19: Overview[26] (August 7, 2020)	The Government of Canada outlines its overall approach to facilitate timely patient access to drugs and vaccines for COVID-19 while ensuring adequate evidence of safety, efficacy, and quality. Information is provided regarding the government's approach to expediting authorization of clinical trials, prioritization of Health Canada reviews for market authorization, and the procedures in place for the Special Access Program.

Organization, title of resource (date)	Brief description or statement
Government of Canada Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19: Notice[27] (May 27, 2020)	The Government of Canada provides information on the Interim Order, approved by the Minister of Health, on May 23, 2020. The Interim Order "introduces an alternate pathway to facilitate clinical trials for potential COVID-19 drugs and medical devices, while upholding strong patient safety requirements and validity of trial data."
Government of Canada Health Canada's regulatory response to COVID-19: International engagement[28] (August 5, 2020)	The Government of Canada outlines ongoing collaborations with international regulators and global health organizations to anticipate and meet the health product needs for Canadians during the COVID-19 pandemic.
International resources	
WHO WHO Target Product Profiles for COVID-19 Vaccines[29] (Version 3, April 29, 2020)	WHO developed a Target Product Profile for COVID-19 vaccines. This document describes the preferred and minimally acceptable criteria for select vaccine characteristics to guide and prioritize the development of COVID-19 vaccines.
WHO Accelerating a safe and effective COVID-19 vaccine[30]	WHO highlights four critical elements of its global research and development efforts for COVID-19 vaccines.
National Institutes of Health Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)[31]	The National Institute of Health outlines the ACTIV initiative, highlighting four fast-track focus areas.
U.S. Food and Drug Administration (FDA) Coronavirus (COVID-19) | CBER-Regulated Biologics[32] (July 2, 2020)	The FDA's Center for Biologics Evaluation and Research (CBER) outlines how it is addressing the COVID-19 pandemic. This includes expediting clinical trials for vaccines for COVID-19.
European Medicines Agency (EMA) Guidance for medicine developers and companies on COVID-19[33]	EMA provides details on accelerated procedures for COVID-19 treatments and vaccines.

Organization, title of resource (date)	Brief description or statement
International Coalition of Medicines Regulatory Authorities (ICMRA) Global regulatory workshop on COVID-19 vaccine development[34] (March 18, 2020)	A global regulatory meeting involving delegates from 17 countries was held on March 18, 2020 to discuss regulatory strategies to facilitate the development of vaccines for COVID-19. The summary report outlines the meeting highlights.
Other tools for tracking COVID-19 vaccine trials	
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