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Trial Title: 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.

Study Reference: ChAdOx1 nCoV-19_ZA_phI/II

Protocol Version: South Africa version 4.1

Date: ZA_30th September 2020

Trial registration: Clinicaltrials.gov: NCT04444674;
Pan African Clinical Trial Registry: PACTR202006922165132.

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Sponsor: University of Oxford

Funder: UK Research and Innovation (For Vaccine supply only)
Funding: The Bill and Melinda Gates Foundation
and South African Medical Research Council

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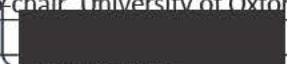
Investigator agreement

The principal investigator is responsible for ensuring that all study site personnel, including sub-investigators and other staff members, conduct this trial according to this protocol, Good Clinical Practice (GCP) and International Conference on Harmonization (ICF) guidelines, the Declaration of Helsinki and the pertinent country laws and regulations and to comply with its obligations, subject to ethical and safety considerations during and after the trial completion. The principal investigator also agrees not to disclose the information contained in this protocol or any results obtained from this trial without written authorization.


I have read and approve the protocol specified above and agree in its content:

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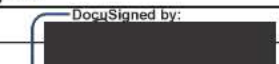
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Trial Title	An adaptive phase I/II randomized placebo-controlled trial to determine safety, immunogenicity and efficacy of non-replicating ChAdOx1 SARS-CoV-2 vaccine in South African adults living without HIV; and safety and immunogenicity in adults living with HIV
Trial Identifier	ChAdOx1 nCoV-19_ZA_phI/II
Trial Registration	Clinicaltrials.gov: NCT04444674; Pan African Clinical Trial Registry: PACTR202006922165132
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Clinical Phase	I/II
Design	Double -blinded, randomised, placebo controlled, multi-centre
Population	Healthy adults aged 18-65 years, living with and without HIV
Planned Sample Size	2070 (possible upward adjustment for efficacy endpoint)
Planned Trial Duration:	Regular visits from enrolment through to at least 12 months later.

Summary table of groups

Group #	Group description	Objective	Follow up	Treatment	Vaccination schedule
1 (n=70)	People without HIV (HIV-uninfected)	Intensive Safety and immunogenicity	Intensive	ChAdOx1 nCoV-19 5-7.5x10 ¹⁰ vp; OR Normal saline (0.9% NaCl)	2* doses, 4 weeks (21-35 days) apart
2a (n=250) [§]	People without HIV (HIV-uninfected)	Safety, intensive immunogenicity and vaccine efficacy	Extended	ChAdOx1 nCoV-19 5-7.5x10 ¹⁰ vp; OR Normal saline (0.9% NaCl)	2* doses, 4 weeks (21-35 days) apart
2b (n=1650) [§]	People without HIV (HIV-uninfected)	Safety, immunogenicity and vaccine efficacy	Extended	ChAdOx1 nCoV-19 5-7.5x10 ¹⁰ vp; OR Normal saline (0.9% NaCl)	2* doses, 4 weeks (21-35 days) apart
3 (n=100)	People living with HIV (HIV-infected)	Intensive Safety and immunogenicity	Intensive	ChAdOx1 nCoV-19 5-7.5x10 ¹⁰ vp; OR Normal saline (0.9% NaCl)	Prime-boost 2* doses, 4 weeks (21-35 days) apart

*Participants will receive 2 doses of the same injection (EITHER IP or placebo) as assigned at randomization.

[§]Numbers will be increased to supplement for corresponding number of individuals randomized prior to implementation of Version 3.0 of the protocol that tested positive for SARS-CoV-2 on PCR at time of randomization.

[#] Following review of the initial safety/immunogenicity phase I trial conducted in the UK; COV0001 trial, and after review of the initial safety/ immunogenicity trial COV0001 by the DSMC; it was confirmed that Group 2 participants will receive 2 doses. SAHPRA and WHREC had been informed of this decision based on the earlier protocol requirements. Also, considering the unpredictability of the force of SARS-CoV-2 infection and the lower than anticipated attack rate for the primary-endpoint cases in the study being undertaken in the UK, the sample size for Group 2 (efficacy cohort) was expanded from the 550 included in protocol version 1.0, dated 24th April 2020. This will involve enrolling up to a total of 1900 people in Group-2, which will provide 80% power to detect at least a 60% vaccine efficacy (lower bound of 95%CI >0) with an attack rate of 3.5% in the placebo arm. Ongoing review of the number of COVID-19 endpoint cases accrued during the course of the study, may lend itself to enrolling smaller number of participants should the attack rate be higher than 3.5%. The sample size for Group-1 has been increased to 70 to accommodate for the higher than anticipated infection rate with SARS-CoV-2 (6 of initial 24 randomized subjects in Group-1). Similarly, in anticipation of approximately one-third of Group-3 participants possibly being already infected with SARS-CoV-2, the sample size will be increased to 100 to have approximately 30 sero-negative vaccinees and placebo recipients enrolled into the study.

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Visit schedule, group 1 and 3

Visit number	Screening	V1	V2	V3	V4	V5	V6*	V7*	V8*	V9*	V10	V11	COVID-19
Day #	-14 to -1	0 (Vax1)	3	7	14	28 (Vax2)	31	35	42	56	182	364	Illness
	Screening	D0	V1+ 3 days ±1; (day 2-4)	V1 +7 days ±2 (day 5-9)	V1+ 14 days ±3 (day 11-17)	Visit 1 + 28 days ±7 (day 21-35)	V5+3 days ±1	V5+7 days ±2	V5+14 days ±3	V5 +28 (±7)	D182 (±14)	D364 (±14 days)	As required ⁵
Eligibility	X	X											
Consenting	X ⁵	X ⁵											
Inclusion/ exclusion	X	X				X							
Contraindications	X	X				X							
Vital signs [#]	X	X	X	X	X	X	X	X	X	X	X	X	X
Medical history	X												X
Physical examination	X (full)	X	X	X	X	X (full)	X	X	X	X	X	X	X (full)
Vaccination		X				X							
Post-vaccination obs		X	X (deltoid)	X (deltoid)		X	X (deltoid)	X (deltoid)					
Diary cards provided		X				X							X (illness DC)
DC collected				X				X					
Safety bloods (FBC, U&E, LFT)	X		X	X		X		X		X			
Screening bloods (HBsAg, HIV, HbA1C)	X											X (HIV Gr 1)	
HIV Viral load and CD4 (Grp 3 only)	VL and CD4												
Immunology bloods***		E, PAX (15.0-20.0ml)	Cyt, PAX (15.0 -20.0l)		E & CMI (20-25ml)	E, N, PAX (20.0-25.0ml)		Cyt (10-15mls)	E & N & CMI (25-30ml)	E (10-15ml)	E (10-15ml)	E & N (15-20ml)	E (10-20ml)
Urinalysis	X												
Urinalysis bHCG (women only)	X	(X)				X							
Nasal swab/ saliva	X (V1-96 hours)	X		X	X	X		X	X	X	X	X	X

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- Visit 5 to Visit 9 are scheduled relative to when the 2nd dose of vaccine/placebo (Visit 4) has been administered.

§ Screening informed consent form (ICF).

¥ Full study participation informed consent form, if remain eligible after completion of screening procedures.

Vital signs includes pulse, respiratory rate, oxygen saturation, blood pressure and temperature;

** Timeline is approximate only. Exact timings of visits relate to the day on enrolment, i.e., each visit must occur at indicated number of days after enrolment ± time window

*** Abbreviations for laboratory tests: E =Elisa; Cyt= Th1 and Th2 cytokine profile; N= neutralization and/or pseudo-neutralisation assay; CMI= cell-mediated immunity assay, PAX= PAXgenes.

Blood test summary:

- Screening: Safety bloods (Full Blood Count, FBC; Urea and Electrolytes, U&E; Liver Function tests, LFT); Screening bloods (HBsAg, HIV, Glycosylated hemoglobin; HbA1c), In group 3 only- CD4+ -lymphocyte count, CD4+ & VHIV-1 viral load, VL)
- Visit 1: Immunogenicity- Elisa
- Visit 2: Safety bloods (FBC, U&E, LFT), Immunogenicity- Th1 and Th2 cytokine profile
- Visit 3: Safety bloods (FBC, U&E, LFT)
- Visit 4: Immunogenicity- Elisa & cell-mediated immunity
- Visit 5: Safety bloods (FBC, U&E, LFT), Immunogenicity- Elisa & neutralization and/or pseudo-neutralisation assay
- Visit 6: NIL
- Visit 7: Safety bloods (FBC, U&E, LFT), Immunogenicity- Th1 and Th2 cytokine profile
- Visit 8: Immunogenicity- Elisa, neutralization and/or pseudo-neutralisation assay & cell-mediated immunity
- Visit 9: Safety bloods (FBC, U&E, LFT), Immunogenicity- Elisa
- Visit 10: Immunogenicity- Elisa
- Visit 11: Immunogenicity- Elisa & neutralization and/or pseudo-neutralisation assays
- Illness visit Immunogenicity- Elisa

§ Nasal swabs/ saliva and Elisa (illness) will be repeated at Days 5-8, 12-15 and 28-35 days.

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Visit schedule, group 2a (first 250 participants)

Visit number	Screening	V1	V2	V3	V4	V5*	V6*	V7*	V8	V9	COVID-19
Day #	-14 to -1	0 (Vax1)	7	14	28 (Vax2)	35	42	56	182	364	Illness
	Screening	D0	V1 +7 days ±2 (day 5-9)	V1+ 14 days ±3 (day 11-17)	Visit 1 + 28 days ±7	V4+7 days ±2	V4+14 days ±3	V4 +28 (±7)	D182 (±14)	D364 (±14 days)	As required ⁵
Eligibility	X	X									
Consenting	X [§]	X [‡]									
Inclusion/ exclusion	X	X			X						
Contraindications	X	X			X						
Vital signs [#]	X	X	X	X	X	X	X	X	X	X	X
Medical history	X										X
Physical examination	X (full)	X	X	X	X (full)	X	X	X	X	X	X (full)
Vaccination		X			X						
Post-vaccination obs		X	X (deltoid)		X	X (deltoid)					
Diary cards provided		X			X						X (illness DC)
DC collected			X			X					
Screening bloods (HBsAg, , HIV, HbA1C)	X									X (HIV)	
Immunology bloods***		E, PAX (15.0- 20.0)	Cyt, PAX (15.0 -20.0ml)	E & CMI (20-25ml)	E, N, PAX (20.0-25.0ml)		E & N & CMI (25-30ml)	E (10-15ml)	E (10-15ml)	E & N (15-20ml)	E (10-20ml)
Urinalysis	X										
Urinalysis bHCG (women only)	X	(X)			X						
Nasal swab/ saliva	X (V1-96 hours)	X	X	X	X	X	X	X	X	X	X

* Visit 5 to Visit 7 are scheduled relative to when the 2nd dose of vaccine/placebo (Visit 4) has been administered.

[§] Screening informed consent form (ICF).

[‡] Full study participation informed consent form, if remain eligible after completion of screening procedures.

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#Vital signs includes pulse, respiratory rate, oxygen saturation, blood pressure and temperature;

** Timeline is approximate only. Exact timings of visits relate to the day on enrolment, i.e., each visit must occur at indicated number of days after enrolment \pm time window

***Abbreviations for laboratory tests: E=Elisa; Cyt=Th1 and Th2 cytokine profile; N=neutralization and/or pseudo-neutralisation assay; CMI= cell-mediated immunity assay.

Blood test summary:

- Screening: Screening bloods (HBsAg, HIV, HBA1C)
- Visit 1: Immunogenicity- Elisa
- Visit 2: Immunogenicity- Th1 and Th2 cytokine profile
- Visit 3: Immunogenicity- Elisa & cell-mediated immunity assay
- Visit 4: Immunogenicity- Elisa & neutralization and/or pseudo-neutralisation assay, PAX- HLA
- Visit 5: Nil
- Visit 6: Immunogenicity- Elisa, neutralization and/or pseudo-neutralisation assay & cell-mediated immunity assay
- Visit 7: Immunogenicity- Elisa
- Visit 8: Immunogenicity- Elisa
- Visit 9: Immunogenicity- Elisa & neutralization and/or pseudo-neutralisation assay
- Illness visit Immunogenicity- Elisa

[§] Nasal swabs/ saliva and Elisa (illness) will be repeated at Days 5-8, 12-15 and 28-35 days

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Visit schedule, group 2b (extended efficacy cohort; remaining 1650 participants)

Visit number	Screening	V1	V2	V3	V4	V5	V6	COVID-19
Day #	-14 to -1	0 (Vax1)	28 (Vax2)	42	56	182	364	Illness
	Screening	D0	Visit 1 + 28 days ±7	V2+14 days ±3	V2 +28 (±7)	D182 (±14)	D364 (±14 days)	As required ⁵
Eligibility	X	X						
Consenting	X [§]	X*						
Inclusion/ exclusion	X	X	X					
Contraindications	X	X	X					
Vital signs *	X	X	X	X	X	X	X	X
Medical history	X							X
Physical examination	X(full)	X	X (full)	X	X	X	X	X (full)
Vaccination		X	X					
Post vaccination Obs		X	X					
Diary cards provided		X	X					X (illness DC)
DC collected			X					
Screening bloods (HBsAg, HIV, HbA1C)	X						X (HIV)	
Immunology bloods***		E (15-20 ml)	E, N, HLA (20-25 ml)	E & N (15-20ml)	E (10-15ml)	E (10-15ml)	E & N (15-20ml)	E (10-20ml)
Urinalysis	X							
Urinalysis bHCG (women only)	X	(X)	X					
Nasal swab/ saliva	X (V1-96 hours)	X	X	X	X	X	X	X

[§] Screening informed consent form (ICF).

*Full study participation informed consent form, if remain eligible after completion of screening procedures.

*

Vital signs includes pulse, respiratory rate, oxygen saturation, blood pressure and temperature;

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** Timeline is approximate only. Exact timings of visits relate to the day on enrolment, i.e., each visit must occur at indicated number of days after enrolment \pm time window

***Abbreviations for laboratory tests: E=Elisa; Cyt=Th1 and Th2 cytokine profile; N=neutralization and/or pseudo-neutralisation assay; CMI=cell-mediated immunity assay.

Blood test summary:

- Screening: Screening bloods (HBsAg, HIV, HbA1C)
- Visit 1: Immunogenicity- Elisa
- Visit 2 Immunogenicity- Elisa & neutralization and/or pseudo-neutralisation assay, HLA
- Visit 3 Immunogenicity- Elisa, neutralization and/or pseudo-neutralisation assay
- Visit 4 Immunogenicity- Elisa,
- Visit 5 Immunogenicity- Elisa
- Visit 6 Immunogenicity- Elisa & neutralization and/or pseudo-neutralisation assay
- Illness visit Immunogenicity- Elisa

\$ Nasal swabs/ saliva and Elisa (illness) will be repeated at Days 5-8, 12-15 and 28-35 days.

Objectives:**In adults without HIV (HIV-uninfected)****Primary objective:**

To assess the safety of the candidate vaccine ChAdOx1 nCoV-19 in healthy HIV-uninfected adults.

Co-primary objective:

To assess efficacy of the candidate ChAdOx1 nCoV-19 against COVID-19, defined as virologically confirmed (PCR positive) COVID-19 disease, in participants that were COVID-19 naïve at time of randomization and who received two doses of ChAdOx1 nCoV-19 or placebo. Events will be included if they occurred more than 14 days after the booster dose. "COVID-19 naïve" will be defined as sero-negative and tested negative for SARS-CoV-2 infection based on a high sensitivity serology antibody test and molecular detection testing of nasal swab, respectively

Secondary objective

To assess the immunogenicity of ChAdOx1 nCoV-19 in healthy HIV-uninfected adults

Details of objectives Groups 1 & 2 (HIV-uninfected):

Objective	Objective details	Endpoint measures
Primary Objective (Group 1 and Group 2)	To assess the safety, tolerability and reactogenicity profile of the candidate vaccine ChAdOx1 nCoV-19	a) occurrence of solicited local reactogenicity signs and symptoms for 7 days following vaccination; b) occurrence of solicited systemic reactogenicity signs and symptoms for 7 days following vaccination; c) occurrence of unsolicited adverse events (AEs) for 28 days following vaccination; d) change from baseline for safety laboratory measures and; e) occurrence of serious adverse events e) occurrence of disease enhancement episodes

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Co- Primary objective (Group 2a and 2b; efficacy cohort)	To assess efficacy of the candidate ChAdOx1 nCoV-19 against mild to severe COVID-19	The primary efficacy [objective] and endpoint include PCR positive COVID-19 disease cases occurring in participants that were COVID-19 naïve at the time of randomization and who received at least two doses of ChAdOx1 nCoV-19 or placebo. Events will be included if they occurred more than 14 days after the booster dose. Virologically-confirmed COVID-19 clinical disease will be defined as an acute respiratory illness that is clinically consistent with COVID-19 based on presence of:	
		New onset systemic	Endpoint Definitions
		Mild	Any one of: <ul style="list-style-type: none">Fever (defined by subjective or objective measure, regardless of use of anti-pyretic medications)New onset cough≥ 2 COVID-19 respiratory/non-respiratory symptoms, AND
		Moderate	≥ 1 of: <ul style="list-style-type: none">Fever (≥ 37.8°C) + any 2 COVID-19 symptoms for ≥ 3 days (need not be contiguous days)High fever (≥ 38.4°C) for ≥ 3 days (need not be contiguous days)Any evidence of significant LRTI: Shortness of breath (or breathlessness or difficulty breathing) with or without exertion (beyond baseline) Tachypnea: 20 to 29 breaths per minute at rest SpO2: < 94% on room air Abnormal chest x-ray/CT consistent with pneumonia or LRTI
		Severe	≥ 1 of: <ul style="list-style-type: none">Tachypnea: ≥ 30 breaths per minute at restSpO2: < 92% on room air or PAO2/FiO2 < 300High flow oxygen therapy, CPAP, or NIV (eg, CPAP/BiPAP)Mechanical ventilation or ECMOOne or more major organ system failure^a (eg, cardiac/circulatory, pulmonary, renal, hepatic to be

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Secondary objectives (Group 2)	To assess the efficacy of the candidate ChAdOx1 nCoV-19 against COVID-19 of differing severity	<p>All secondary VE analyses will be done for the overall population and stratified by COVID-19 serological status at baseline.</p> <ul style="list-style-type: none"> a. VE in preventing virologically-confirmed COVID-19 clinical disease including all cases occurring onward from 21 days after a single dose. b. VE in preventing virologically-confirmed COVID-19 clinical disease occurring more than 14 days after a second dose for the overall population and those that were sero-positive at baseline.. c. VE in preventing PCR positive COVID-19 disease cases. d. VE in preventing moderate-severe virologically confirmed COVID-19 disease. e. VE in preventing severe confirmed COVID-19 disease. f. VE in preventing LRTI associated with virologically-confirmed COVID-19 clinical disease g. VE in preventing hospitalization due to virologically confirmed COVID-19 disease h. VE in preventing all-cause LRTI (overall and stratified by hospitalization or not) irrespective of test result for SARS-CoV-2. i. h. VE using Oxford Primary Outcome definition (PCR+ at least one symptom of fever > 37.8°C, cough, shortness of breath, anosmia, aguesia).
Secondary objective (Group 1 and Group 2)	To assess cellular and humoral immunogenicity of ChAdOx1 nCoV-19	<ul style="list-style-type: none"> a) Enzyme-linked immunosorbent assay (ELISA) or fluorescence based micro-bead immunosorbent assay on luminex platform to quantify antibodies against SARS-CoV-2 spike protein (sero-conversion rates) b) Interferon-gamma (IFN-γ) enzyme-linked immunospot (ELISpot) responses to SARS-CoV-2 spike protein c) Virus neutralising antibody (NAb) assays against live and/or pseudotyped SARS-CoV-2 virus d) Th1 and Th2 cytokine response profile at 3-4 days after vaccination.
Exploratory immunology:	To assess B cell responses to SARS-CoV-2 spike trimer and/or the receptor binding domain	<ul style="list-style-type: none"> a. Cellular Fc effector functionality assays to measure the ability of vaccine elicited antibodies to mediate cellular cytotoxicity, complement deposition, and phagocytosis. b. Flow cytometric sorting of plasmablasts and memory B cells to using spike and receptor binding domain "baits" to isolate SARS-CoV-2 specific B cells, sequence their immunoglobulin genes and define their epitope specificity.

In adults living with HIV (HIV-infected)**Primary co-objectives:**

- To assess the safety of the candidate vaccine ChAdOx1 nCoV in adults living with HIV.
- To evaluate the immunogenicity of ChAdOx1 nCoV-19 after first and second doses of vaccine.

Details of objectives Group 3 (HIV-infected):

	Objective details	Endpoint measures
Primary objective	To assess the safety, tolerability and reactogenicity profile of the candidate vaccine ChAdOx1 nCoV-19 in people living with HIV	a) occurrence of solicited local reactogenicity signs and symptoms for 7 days following vaccination; b) occurrence of solicited systemic reactogenicity signs and symptoms for 7 days following vaccination; c) occurrence of unsolicited adverse events (AEs) for 28 days following vaccination; d) change from baseline for safety laboratory measures and; e) occurrence of serious adverse events e) occurrence of disease enhancement episodes
Co-primary objective	To assess cellular and humoral immunogenicity of ChAdOx1 nCoV-19 in people living with HIV after one and two doses of vaccine	a) Enzyme-linked immunosorbent assay (ELISA) or fluorescence based micro-bead immunosorbent assay on luminex platform to quantify antibodies against SARS-CoV-2 spike protein (seroconversion rates) b) Interferon-gamma (IFN- γ) enzyme-linked immunospot (ELISpot) responses to SARS-CoV-2 spike protein c) Virus neutralising antibody (NAb) assays against live and/or pseudotyped SARS-CoV-2 virus d) Th1 and Th2 cytokine response profile at 3-4 days after vaccination.

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Secondary objective	To descriptively compare immune responses to ChAdOx1 nCoV-19 in people living with HIV to HIV-uninfected individuals, overall and stratified by COVID-19 sero-status at enrolment.	<p>a) Enzyme-linked immunosorbent assay (ELISA) or fluorescence based micro-bead immunosorbent assay on luminex platform to quantify antibodies against SARS-CoV-2 spike protein (seroconversion rates)</p> <p>b) Interferon-gamma (IFN-γ) enzyme-linked immunospot (ELISpot) responses to SARS-CoV-2 spike protein</p> <p>c) Virus neutralising antibody (NAb) assays against live and/or pseudotyped SARS-CoV-2 virus</p> <p>d) Th1 and Th2 cytokine response profile at 3-4 days after vaccination.</p>
Exploratory immunology	To assess B cell responses to SARS-CoV-2 spike trimer and/or the receptor binding domain	<p>a. Cellular Fc effector functionality assays to measure the ability of vaccine elicited antibodies to mediate cellular cytotoxicity, complement deposition, and phagocytosis.</p> <p>b. Flow cytometric sorting of plasmablasts and memory B cells to using spike and receptor binding domain "baits" to isolate SARS-CoV-2 specific B cells, sequence their immunoglobulin genes and define their epitope specificity.</p>

Formulation Liquid

Investigational products

- ChAdOx1 nCoV-19, a non-replicating simian adenoviral vector expressing the spike (S) protein of SARS-CoV-2 (investigational product, IP)
- Normal saline, NaCl 0.9% as placebo

Route of Administration Intramuscularly (IM) into the deltoid region of the non-dominant arm

Dose per Administration ChAdOx1 nCoV-19 $5-7.5 \times 10^{10}$ vp

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2. ABBREVIATIONS

AdHu	Human adenovirus
AdHu5	Human adenovirus serotype 5
AE	Adverse event
AID	Autoimmune Disease
CCVTM	Centre for Clinical Vaccinology and Tropical Medicine, Oxford
CBF	Clinical Bio manufacturing Facility
CEF	Chick embryo fibroblast
ChAd63	Chimpanzee adenovirus 63
CI	Confidence interval
COP	Code of Practice
CRF	Case Report Form or Clinical Research Facility
CS or CSP	Circumsporozoite protein
CTRG	Clinical Trials & Research Governance Office, Oxford University
CTL	Cytotoxic T Lymphocyte
DSUR	Development Safety Update Report
ELISPOT	Enzyme-linked immunospot
GCP	Good Clinical Practice
GMO	Genetically modified organism
GMT	Geometric Mean Titre
GP	General Practitioner
GSK	GlaxoSmithKline
HCG	Human Chorionic Gonadotrophin
HBV	Hepatitis B virus
HEK	Human embryonic kidney
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HLA	Human leukocyte antigen
HRA	Health Research Authority
HREC	Human Research Ethics Committee
HTLV	Human T-Lymphotropic Virus
IB	Investigator Brochure
ICH	<i>International Conference on Harmonisation</i>
ICMJE	<i>International Committee of Medical Journal Editors</i>
ICS	<i>Intracellular Cytokine Staining</i>
IDT	Impfstoffwerk Dessau-Tornau Biologika GmbH
ID	Intradermal
IFNγ	Interferon gamma
IM	Intramuscular
IMP	Investigational Medicinal Product
IMP-D	Investigational Medicinal Product Dossier
IP	Investigational Product
IV	Intravenous
LSOC	Local safety oversight clinician
ME-TRAP	Multiple epitopes and thrombospondin related adhesion protein
MVA	Modified vaccinia virus Ankara

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NANP	N-acetylneuraminic acid phosphatase
NHLS	National Health Laboratory Service
NICD	National Institute for Communicable Diseases
PBMC	<i>Peripheral blood mononuclear cell</i>
Pb	<i>Plasmodium Berghei</i>
PCR	Polymerase chain reaction
PI	Principal Investigator
pfu	Plaque forming unit
QP	Qualified Person
qPCR	Quantitative polymerase chain reaction
QS21	<i>Quillaja saponaria</i> saponin molecule
REC	Research Ethics Committee
SAE	Serious adverse event
SAHPRA	South African Health Products Regulatory Authority
SC	Subcutaneous
SmPc	Summary of Product characteristics
SOP	Standard Operating Procedure
SUSAR	Suspected unexpected serious adverse reaction
µg	microgram
vp	viral particle
VV	viral vector
WHO	World Health Organization