

# Observational cohort trial of immune response in patients with chronic health conditions following coronavirus vaccination

<b>Submission date</b> 15/02/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 17/02/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/06/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-see-how-the-covid-19-vaccination-affects-how-the-body-fights-infection-octave>

### Background and study aims

The rapid development and subsequent authorisation of vaccines against coronavirus (formal name SARS-CoV-2) has been a major step forward for medical science. The participants of developmental vaccine trials were generally healthy volunteers and questions remain as to the level of protection these vaccines will afford patients with chronic illnesses who may have deficiencies in their immune system and may not generate the same protective responses observed in healthy volunteers.

In summer 2021 COVID-19 vaccines started to be offered to young immune-suppressed people, aged 12 to 17 years. The rollout of COVID-19 vaccines to immune suppressed 5 to 11-year-old children began in February 2022 in all four nations. To help work out optimal vaccine schedules, the OCTAVE trial has been expanded to include these younger participants. These participants were excluded from the existing studies of SARS-CoV-2 vaccines in those aged between 5 and 17 years and 364 days.

The aim is to evaluate the way the body defends itself against coronavirus (the immune response) following vaccination in clinically vulnerable groups.

### Who can participate?

Adult groups (18 years or above): patients with end-stage kidney disease, liver disease or gastrointestinal disease on immune suppressive therapy, cancer, immune-mediated rheumatic diseases (e.g. rheumatoid arthritis) and stem cell transplant recipients who are receiving the COVID-19 vaccine as part of the national vaccination programme.

Children and adolescents group (aged 5 to 17 years): patients who are immune-suppressed due to medication following solid organ transplantation, with immune-mediated rheumatic diseases, or due to treatment for cancer or cancer itself who are receiving the COVID-19 vaccine as part of the national vaccination programme. Trial entry may precede either first, second, third or fourth vaccine dose.

What does the study involve?

Blood and saliva samples will be collected at the following time points:

Deep immunophenotyping Group:

- Before the first injection (unless the participant has already donated a blood sample as part of another study and these are available for use in OCTAVE)
- The day after the first injection (this is optional)
- Before the boost injection
- 28 days after the boost injection
- 6 months after the second injection
- 12 months after the first injection

Serology Group:

- Before the first injection (where this is possible)
- 28 days after the boost injection

Serology Plus Group:

- Before the injection of vaccine being given at trial entry. This may be the first, second, third or fourth injection of the vaccine depending on how many doses of vaccine they have received before entering the study.
- 28 days after the injection (-7/+56 days)
- If the participant has another injection of vaccine during the study, 28 days after this injection (-7/+56 days)
- 6 months after the most recent injection

What are the possible benefits and risks of participating?

There may be no direct benefit to the participants from taking part in this study. The information gained from this study may help to improve the way in which patients with chronic health conditions and cancer are vaccinated for coronavirus in the future.

Participants may need to go to hospital more frequently to have blood samples taken. How many extra visits are needed will depend on the patient's condition and how frequently they are currently being seen by their doctor. Where possible the study doctor and research nurse will try to limit the number of extra visits needed.

Having blood taken may cause some discomfort, bleeding or bruising where the needle enters the body and, in rare cases, light-headedness and fainting.

Where is the study run from?

The study is being run by the Cancer Research UK Clinical Trials Unit at the University of Birmingham (UK)

When is the study starting and how long is it expected to run for?

January 2021 to June 2025

Who is funding the study?

This research is funded by the Medical Research Council (UK)

Who is the main contact?

OCTAVE Trial Office

OCTAVE@trials.bham.ac.uk

## Contact information

Type(s)

Public

**Contact name**

Dr Ann Pope

**Contact details**

Cancer Research UK Clinical Trials Unit  
Institute of Cancer & Genomic Sciences  
University of Birmingham  
Edgbaston  
Birmingham  
United Kingdom  
B15 2TT  
+44 (0)121 4143100  
octave@trials.bham.ac.uk

**Type(s)**

Scientific

**Contact name**

Prof Iain McInnes

**ORCID ID**

<https://orcid.org/0000-0002-6462-4280>

**Contact details**

University of Glasgow  
Wolfson Medical School Building  
University Avenue  
Glasgow  
United Kingdom  
G12 8QQ  
+44 (0)141 332378  
Iain.McInnes@glasgow.ac.uk

**Additional identifiers****Clinical Trials Information System (CTIS)**

2021-000569-33

**Integrated Research Application System (IRAS)**

294480

**Protocol serial number**

MX1034, sponsor number RG\_21-007

**Study information****Scientific Title**

Observational Cohort Trial-T-cells Antibodies and Vaccine Efficacy in SARS-CoV-2

## **Acronym**

OCTAVE

## **Study objectives**

Current study hypothesis as of 02/08/2022:

The rapid development and subsequent authorisation of vaccines against coronavirus (formal name SARS-CoV-2) has been a major step forward for medical science. The participants of developmental vaccine trials were generally healthy volunteers and questions remain as to the level of protection these vaccines will afford patients with chronic illnesses who may have deficiencies in their immune system and may not generate the same protective responses observed in healthy volunteers.

In summer 2021 COVID-19 vaccines started to be offered to young immune-suppressed people, aged 12 to 17 years. The rollout of COVID-19 vaccines to immune-suppressed 5 to 11-year-old children began in February 2022 in all four nations. To help work out optimal vaccine schedules, the OCTAVE trial has been expanded to include these younger participants. These participants were excluded from the existing studies of SARS-CoV-2 vaccines in those aged between 5 and 17 years and 364 days.

The aim is to evaluate the way the body defends itself against coronavirus (the immune response) following vaccination in clinically vulnerable groups.

Previous study hypothesis:

The rapid development and subsequent authorisation of vaccines against coronavirus (COVID-19) has been a major step forward for medical science. In the UK, three vaccines are already approved by the regulatory agency, Pfizer/BioNTech, AstraZeneca, and Moderna. It is likely that further vaccines will become available in the coming months. National vaccination programmes have been initiated in the UK for Pfizer-BioNtech and the Astra-Zeneca vaccines. The populations evaluated in the trials of these vaccines were generally healthy volunteers. Therefore questions remain as to the level of protection these vaccines will afford patient populations with chronic healthcare conditions who may have immune deficiencies and, therefore, may not generate the same protective responses observed in healthy volunteers.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 12/02/2021, London-Chelsea Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 1048029; chelsea.rec@hra.nhs.uk), ref: 21/HRA/0489

## **Study design**

Multi-centre multi-disease prospective observational cohort trial

## **Primary study design**

Observational

## **Study type(s)**

Other

## **Health condition(s) or problem(s) studied**

Adult groups (18 years or above): patients with end-stage kidney disease, liver disease or gastrointestinal disease on immune suppressive therapy, cancer, immune-mediated rheumatic diseases (e.g. rheumatoid arthritis) and stem cell transplant recipients who are receiving the COVID-19 vaccine as part of the national vaccination programme. Children and adolescents group (aged between 5 and 17 years): patients who are immune-suppressed due to medication following solid organ (heart +/- lung, kidney) transplantation, with immune-mediated rheumatic diseases, or due to treatment for cancer or cancer itself who are receiving the COVID-19 vaccine as part of the national vaccination programme.

## **Interventions**

Current interventions as of 08/08/2022:

Three different groups of research samples are being assessed during the trial:

Deep Immunophenotyping Group - each disease cohort will include 150 participants; blood and saliva samples are being collected at 4-5 time points;

Serology Group – each disease cohort will include up to 850 participants; blood and saliva samples are being collected twice;

Serology Plus Group – comprising three disease cohorts: paediatric cancer, post solid organ transplant and rheumatic/inflammatory conditions; cohorts to include up to 160 participants. Pre- and post-vaccine dose blood samples to be obtained (with a maximum of 4 sample timepoints per participant).

Blood and saliva samples will be collected at the following time points:

Deep immunophenotyping Group:

- Before the first injection (unless the participant has already donated a blood sample as part of another study and these are available for use in OCTAVE)
- The day after the first injection (this is optional)
- Before the boost injection
- 28 days after the boost injection
- 6 months after the second injection
- 12 months after the first injection

Serology Group:

- Before the first injection (where this is possible)
- 28 days after the boost injection

Serology Plus Group – Blood samples only:

- Before the injection of vaccine being given at trial entry. This may be the first, second, third or fourth injection of the vaccine depending on how many doses of vaccine they have received before entering the study.
- 28 days after the injection (-7/+56 days)
- If the participant has another injection of vaccine during the study, 28 days after this injection (-7/+56 days)
- 6 months after the most recent injection

Previous interventions as of 02/08/2022:

Three different groups of research samples are being assessed during the trial:

Deep Immunophenotyping Group - each disease cohort will include 150 participants; blood and saliva samples are being collected at 4-5 time points;

Serology Group – each disease cohort will include up to 850 participants; blood and saliva samples are being collected twice;

Serology Plus Group – comprising three disease cohorts: paediatric cancer, post solid organ transplant and rheumatic/inflammatory conditions; cohorts to include up to 160 participants. Pre- and post-vaccine dose blood samples to be obtained (with a maximum of 4 sample timepoints per participant).

Blood and saliva samples will be collected at the following time points:

Deep immunophenotyping Group:

- Before the first injection (unless the participant has already donated a blood sample as part of another study and these are available for use in OCTAVE)
- The day after the first injection (this is optional)
- Before the boost injection
- 28 days after the boost injection
- 6 months after the first injection

Serology Group:

- Before the first injection (where this is possible)
- 28 days after the boost injection

Serology Plus Group – Blood samples only:

- Before the injection of vaccine being given at trial entry. This may be the first, second, third or fourth injection of the vaccine depending on how many doses of vaccine they have received before entering the study.
- 28 days after the injection (-7/+56 days)
- If the participant has another injection of vaccine during the study, 28 days after this injection (-7/+56 days)

Previous interventions:

Two different groups of research samples are being assessed during the trial: Deep Immunophenotyping Group - each disease cohort will include 150 participants; and the Serology Group – each disease cohort will include up to 850 participants.

Blood and saliva samples are being collected at 4-5 time points for the Deep Immunophenotyping Group and twice for the Serology Group.

Blood and saliva samples will be collected at the following time points:

Deep immunophenotyping Group:

- Before the first injection (unless the participant has already donated a blood sample as part of another study and these are available for use in OCTAVE)
- The day after the first injection (this is optional)
- Before the boost injection
- 28 days after the boost injection
- 6 months after the first injection

## Serology Group:

- Before the first injection (where this is possible)
- 28 days after the boost injection

## Intervention Type

Biological/Vaccine

## Phase

Phase I

## Drug/device/biological/vaccine name(s)

Pfizer/BioNTech, AstraZeneca, and Moderna vaccines

## Primary outcome(s)

1. Anti-SARS-CoV-2 IgG Abs following vaccination will be measured using the Roche platforms. (The Roche assay measures the presence and amount of serum antibodies to both the spike (S) and the nucleocapsid (N) antigens of SARS-CoV-2. This assay will enable the discrimination of IgG responses to SARS-CoV-2 that results from vaccination and/or SARS-CoV-2 infection)
2. T cell responses to SARS-CoV-2 peptides following vaccination will be measured using the Oxford Immunotec modified T-SPOT Discovery SARS-CoV-2 assay. This IFN $\gamma$  ELISpot assay will provide insights into patient reactivity to SARS-CoV-2 S1, S2, Nucleocapsid and membrane peptides.

## Key secondary outcome(s)

Measured following vaccination:

1. First symptomatic, PCR-proven COVID-19 occurrence from 14 days after first dose of SARS-CoV-2 vaccine in participants without evidence of prior infection with SARS-CoV-2 measured using PCR test
2. Humoral Immunogenicity: SARS-CoV-2 IgG (pseudo)neutralisation assays to assess the capacity of vaccine induced SARS-CoV-2 Abs to neutralise/block SARS-CoV-2 infection

Cellular Immunogenicity:

3. The relative contribution of T cell subsets and T cell function will be assessed using intracellular cytokine analysis and flow cytometry (ICCS) - established at Oxford University laboratories
4. Proliferation assays (CTV assay) will evaluate the recall potential of SARS-CoV-2 memory T cells at later (6 month) time points (established at Oxford University laboratories)

Additional assays relevant to immune state and response may be undertaken:

5. Serum antibodies (IgG/IgM/IgA) to important SARS-CoV-2 antigens and SARS-CoV-2 related antigens (including but not limited to SARS, MERS and circulating seasonal coronaviruses: CoV-2 S, NL63 S, CoV-2 N, CoV-1 S, MERS S, HKU1 S, OC43 S, 229E S, CoV-2 RBD) will be measured in an MSD assay or bespoke ELISA established at University of Glasgow laboratories
6. Saliva antibodies (IgG/IgA) to both the spike (S) and the nucleocapsid (N) antigens of SARS-CoV-2 will be measured using an optimised saliva ELISA
7. Flow cytometric characterisation of the circulating immune compartment (e.g. T cells and B cells) will be undertaken
8. T cell and B cell specific responses to defined peptides/stimuli will be undertaken using established ELISpot assays, at Imperial College London and Oxford University laboratories

## Completion date

30/06/2025

# Eligibility

## Key inclusion criteria

Current inclusion criteria as of 02/08/2022:

1. Are eligible for vaccination by one of the SARS-CoV-2 vaccines approved by the MHRA administered in accordance with national guidelines and current versions of the applicable information for healthcare professionals (see Section 7.1) and:
  - 1.1. For the Deep Immunotherapy Group only, have not received the second dose of the vaccine (booster)
  - 1.2. For the Serology Group only, have not passed the 28 days (-7/+56 days) post second vaccine dose (booster)
  - 1.3. For the Serology Plus Group, have not passed 28 days (within -7/+56 days) post second vaccine dose (booster) or up to 6 months post second vaccine dose, including patients who have received a third or further dose in that time period
2. Anticipated life expectancy of 6 months or greater
3. Fall into one (or more) of the following patient cohorts who will meet disease relevant classification, disease state, and staging according to established international standards:
  - 3.1. Diagnosed with any of the following malignancies:
    - 3.1.1. Breast
    - 3.1.2. Lung
    - 3.1.3. Acute Myeloid Leukaemia
    - 3.1.4. Multiple Myeloma
    - 3.1.5. Paediatric Cancer: any diagnosis of cancer in a child (aged 5 to < 18 years):
      - 3.1.5.1. On active treatment
      - 3.1.5.2. Within 6 months of completion of treatment
  - 3.2. Diagnosed with the following rheumatic/inflammatory conditions:
    - 3.2.1. Specialist diagnosis of relevant condition
    - 3.2.2. Established on relevant therapy for  $\geq 30$  days
    - 3.2.3. Meet the definitions in any of the following cohorts:
      - 3.2.3.1. Deep Immunophenotyping Group::
        - 3.2.3.1.1. Methotrexate plus inflammatory arthritis (to include RA, PsA, seronegative arthritis, and spondyloarthritis)
        - 3.2.3.1.2. TNF inhibitors (any) plus inflammatory arthritis (to include RA, PsA, seronegative arthritis, spondyloarthritis)
        - 3.2.3.1.3. Rituximab in patients with AAV
      - 3.2.3.2. Serology Group:
        - 3.2.3.2.1. Methotrexate plus:
          - 3.2.3.2.1.1. inflammatory arthritis (RA, seronegative arthritis and PsA)
          - 3.2.3.2.1.2. psoriasis
        - 3.2.3.2.2. TNF inhibitors (any) plus:
          - 3.2.3.2.2.1. inflammatory arthritis (RA, seronegative arthritis, axSpA and PsA)
          - 3.2.3.2.2.2. psoriasis
          - 3.2.3.2.2.3. Crohn's disease
        - 3.2.3.2.3. IL-17 inhibitors (any), IL-12/23 inhibitors and IL-23 inhibitors plus:
          - 3.2.3.2.3.1. seronegative arthritis (PsA and axSpA)
          - 3.2.3.2.3.2. psoriasis
        - 3.2.3.2.4. IL-6 inhibitors (any) with RA
        - 3.2.3.2.5. JAK inhibitors (any) with RA

- 3.2.3.2.6. Rituximab with RA or AAV
  - 3.2.3.2.7. Any immune modifying treatment with Systemic Lupus Erythematosus (SLE)
  - 3.2.3.3. Serology Plus Group: aged 5 to <18 years at time of recruitment and
    - 3.2.3.3.1. Methotrexate plus inflammatory arthritis with onset under the age of 16 years (also known as juvenile idiopathic arthritis JIA), with or without JIA-uveitis
    - 3.2.3.3.2. TNF inhibitors (any) plus inflammatory arthritis with onset under the age of 16 years (JIA), with or without JIA-uveitis
    - 3.2.3.3.3. IL-6 inhibitors (any) plus inflammatory arthritis with onset under the age of 16 years (JIA), with or without JIA-uveitis
    - 3.2.3.3.4. Any immune modifying treatment with juvenile onset Systemic Lupus Erythematosus (JSLE)
    - 3.2.3.3.5. Rituximab with plus inflammatory arthritis with onset under the age of 16 years (JIA), with or without JIA-uveitis or AAV
  - 3.3. Diagnosed with the following chronic renal conditions:
    - 3.3.1. End stage kidney disease secondary to any cause
    - 3.3.2. Renal transplant following end stage kidney disease
  - 3.4. Diagnosed with the following chronic liver conditions:
    - 3.4.1. Liver cirrhosis
    - 3.4.2. Liver transplantation
    - 3.4.3. Chronic liver disease (of any stage), or gastrointestinal disease on immune suppressive therapy
  - 3.5. Haematopoietic stem cell transplant patients:
    - 3.5.1. Previously treated with autologous or allo-HSCT for any indication and with any conditioning regimens and intensities
    - 3.5.2. Previously treated with CAR-T cell therapies
- Note: HSCT and CAR-T recipients who have received one or two doses of a SARS-CoV-2 vaccine pre-procedure and are receiving re-vaccination post HSCT / CART-T are eligible for recruitment at:-
- 3.5.2.1. Baseline (prior to re-vaccination dose 1) to either Deep Immunophenotyping Group or Serology Group
  - 3.5.2.2. For the Deep Immunophenotyping Group: before they received the second re-vaccination dose (booster)
  - 3.5.2.3. For the Serology Group: up to 28 (-7 /+ 56) days post second re-vaccination (booster) only if 2 doses have been administered post-HSCT / CAR-T procedure.
- 3.6. Post solid organ transplant in 5 to <18 year olds to the Serology Plus group
    - 3.6.1. Post heart, lung, heart-lung, or kidney transplantation and on immune suppressing medication (calcineurin or mTOR inhibitor, plus additional agents)

Previous inclusion criteria:

1. Are eligible for vaccination by one of the SARS-CoV-2 vaccines approved by the MHRA administered in accordance with the UK Government's COVID-19: the green book, chapter 14a and have either:
  - 1.1. Not received the first dose of the vaccine

Or

  - 1.2. Have participated in a study where bloods were taken prior to their first dose of vaccine and the blood samples were stored and are available for analysis in OCTAVE trial
2. Anticipated life expectancy of 6 months or greater
3. Fall into one (or more) of the following patient cohorts who will meet disease relevant classification, disease state, and staging according to established international standards:
  - 3.1. Diagnosed with any of the following malignancies:
    - 3.1.1. Breast
    - 3.1.2. Lung

- 3.1.3. Acute Myeloid Leukaemia
- 3.1.4. Multiple Myeloma
- 3.2. Diagnosed with the following rheumatic/inflammatory conditions:
  - 3.2.1. Specialist diagnosis of relevant condition
  - 3.2.2. Established on relevant therapy for  $\geq 30$  days
- 3.3. Meet the definitions in any of the following cohorts:
  - 3.3.1. The deeply immunophenotyped cohorts:
    - 3.3.1.1. Methotrexate in patients with RA
    - 3.3.1.2. TNF inhibitors (any) in patients with RA
    - 3.3.1.3. Rituximab in patients with AAV
  - 3.3.2. Treatment cohorts:
    - 3.3.2.1. Methotrexate plus:
      - a) inflammatory arthritis (RA and psoriatic arthritis (PsA))
      - b) psoriasis but no inflammatory arthritis
    - 3.3.2.2. TNF inhibitors (any) plus:
      - a) inflammatory arthritis (RA and PsA)
      - b) psoriasis but no inflammatory arthritis
      - c) Crohn's disease but no inflammatory arthritis
    - 3.3.2.3. IL-17 inhibitors (any) plus:
      - a) seronegative arthritis (PsA and axSpA)
      - b) psoriasis but no inflammatory arthritis
    - 3.3.2.4. IL-6 inhibitors (any) with RA
    - 3.3.2.5. JAK inhibitors (any) with RA
  - 3.3.3. Diagnosed with the following chronic renal conditions:
    - 3.3.3.1. End stage kidney disease secondary to any cause
    - 3.3.3.2. Renal transplant following end stage kidney disease
  - 3.3.4. Diagnosed with the following chronic liver conditions:
    - 3.3.4.1. Liver cirrhosis
    - 3.3.4.2. Liver transplantation
    - 3.3.4.3. Chronic liver disease (of any stage), or gastrointestinal disease on immune suppressive therapy
  - 3.3.5. Haemopoietic stem cell transplant patients:
    - 3.3.5.1. Previously treated with autologous or allo-HSCT for any indication and with any conditioning regimens and intensities
    - 3.3.5.2. Previously treated with CAR-T cell therapies

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Total final enrolment**

2812

### **Key exclusion criteria**

Have already received the first dose of the vaccine and have not participated in a study where blood samples taken prior to their first dose of vaccine were stored and are available for analysis in OCTAVE trial

### **Date of first enrolment**

22/02/2021

### **Date of final enrolment**

31/07/2022

## **Locations**

### **Countries of recruitment**

United Kingdom

England

Scotland

### **Study participating centre**

#### **Queen Elizabeth Hospital**

University Hospitals Birmingham NHS Foundation Trust

Mindelsohn Way

Edgbaston

Birmingham

United Kingdom

B15 2GW

### **Study participating centre**

#### **Glasgow Royal Infirmary**

NHS Greater Glasgow and Clyde

Castle Street

Glasgow

United Kingdom

G4 0SF

### **Study participating centre**

#### **St. James's University Hospital**

Leeds Teaching Hospitals NHS Trust

Beckett Street

Leeds

United Kingdom

LS9 7TF

**Study participating centre**

**Hammersmith Hospital**

Imperial College Healthcare NHS Trust  
Du Cane Road  
London  
United Kingdom  
W12 0HS

**Study participating centre**

**John Radcliffe Hospital**

Oxford University Hospitals NHS Foundation Trust  
Headley Way  
Headington  
Oxford  
United Kingdom  
OX3 9DU

**Study participating centre**

**Addenbrooke's Hospital**

Cambridge University Hospitals NHS Foundation Trust  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

**Study participating centre**

**Southampton General Hospital**

University Hospital Southampton NHS Foundation Trust  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

**Study participating centre**

**King's College Hospital**

King's College Hospital NHS Foundation Trust  
Denmark Hill  
London  
United Kingdom  
SE5 9RS

**Study participating centre**  
**Royal Hallamshire Hospital**  
Sheffield Teaching Hospitals NHS Foundation Trust  
Glossop Road  
Sheffield  
United Kingdom  
S10 2JF

**Study participating centre**  
**St George's University Hospital**  
Cranmer Terrace  
London  
United Kingdom  
SW17 0QT

**Study participating centre**  
**Freeman Hospital**  
Freeman Road  
Newcastle Upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**  
**Great Ormond Street Hospital for Children**  
Great Ormond Street  
London  
United Kingdom  
WC1N 3JH

## **Sponsor information**

**Organisation**  
University of Birmingham

**ROR**  
<https://ror.org/03angcq70>

## **Funder(s)**

## Funder type

Research council

## Funder Name

Medical Research Council

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Requests may be received to share the trial data and research samples collected with researchers running other studies in this and other organisations so that they may perform analysis on the data to answer other important questions about vaccination for coronavirus. Such organisations may include universities, NHS and Public Health England or companies involved in health research and may be in this country or abroad. Requests for data to be shared will be approved by the CRCTU senior Management, as per CRCTU Data Sharing Policy, and will only be granted if the necessary procedures and approvals are in place. Any data shared with other researchers will be anonymised.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	version 1.0	10/07/2023	24/07/2023	Yes	No
<a href="#">Results article</a>	adult cohorts	06/07/2023	24/07/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Plain English results</a>			30/06/2025	No	Yes
<a href="#">Preprint results</a>		23/08/2021	31/08/2021	No	No
<a href="#">Protocol file</a>	version 9.0	15/03/2022	14/11/2024	No	No
	Study website				

[Study website](#)

11/11/2025

11/11/2025

No

Yes