SARS-CoV-2 VACCINATION for COVID-19 DISEASE SAFETY STUDY (VAC4COVID STUDY)

First published: 19/11/2021

Last updated: 17/05/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS44124

Study ID

44381

DARWIN EU® study

No

Study countries

United Kingdom

Study description

VAC4COVID is an online study created by MEMO (Medicines Monitoring Unit) Research at the University of Dundee to track all authorised vaccines used to prevent COVID-19 infection. All licensed/authorised vaccines have already been tested extensively for effectiveness and safety in large clinical trials. As with every new medicine, governments and researchers need to keep monitoring how COVID-19 vaccines are working once they are being used in the wider population. This is standard practice and an important part of how medicines and vaccines are regulated. This study will track vaccines to check they are working well. It will be big enough to detect any rare unexpected vaccine side effects. Participation in this study is voluntary and it will not interfere with participants' usual health care. The aim of the study is to monitor the effectiveness and safety of COVID-19 vaccines by gathering information from a large number of participants about their health before and after they are vaccinated. Participants are prompted by email at monthly intervals to state whether they have had any changes in their health and wellbeing. They are also asked if any reported events required emergency care or resulted in hospitalisation. For the four weeks following vaccination, they are asked to provide these updates on their health on a weekly basis, then return to monthly follow-ups for at least 11 months. Participants are asked to provide consent to allow follow-up and investigation of any adverse events they may experience following vaccination against COVID-19.

Study status

Ongoing

Research institutions and networks

Institutions

University of Dundee

United Kingdom

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Institution | Educational Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Thomas MacDonald

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/12/2020

Actual: 16/12/2020

Study start date

Planned: 28/01/2021

Actual: 02/02/2021

Date of final study report
Planned: 31/12/2025

Sources of funding

- Other

More details on funding

University of Dundee

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

ISRCTN -ISRCTN95881792 https://doi.org/10.1186/ISRCTN95881792

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Main study objective:

To examine the use and safety of licensed/authorised COVID-19 vaccination by collecting event data from participants and healthcare professionals before, during and after the vaccination programme. To monitor, detect and report early pre-specified and emergent safety signals in relation to licensed/authorised COVID-19 vaccinations.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prescription event monitoring, post-authorisation cohort safety study (PASS)

Population studied

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

20000

Study design details

Outcomes

Recruit consented cohorts of participants to examine the safety of licensed/authorised COVID-19 vaccinations. Outcomes measures: Number of participants offered vaccination Number of participants vaccinated Numbers and rates of SAEs and AESI occurring in vaccinated and non-vaccinated participants, Collect participant self-reported data via questionnaires using electronic data capture. Collect demographics of vaccinated and unvaccinated (unexposed) participants. Collect demographics of vaccinated and unvaccinated (unexposed) participants. Collate and analyse licensed/authorised vaccine utilisation characteristics for the whole vaccinated cohort.

Data analysis plan

We will conduct frequent interim analyses (at intervals to be determined in collaboration with medicines safety regulators) to detect signals in the data as it accumulates (Phase 1), and further, more detailed analyses when the study is complete (Phase 2). For each primary outcome we will plot cumulative hazards (-log(survival rate), with confidence intervals) for: vaccinated patients, with date of vaccination as time 0, and unvaccinated patients, with date of

recruitment as time 0 and censored at vaccination. We will also plot the cumulative hazards based on an external estimate of population incidence rates (a straight line).

Documents

Study, other information

VAC4COVID Advisory Committee Charter v1 (e-signed 22-02-21).pdf (94.33 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Disease registry

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No