An Assessment of a relationship between the exposure to COVID-19 vaccines and risk of thrombotic thrombocytopenia syndrome (Association of the risk for Thrombotic Thrombocytopenia Syndrome and Exposure To COVID-19 vaccines) - ATTEST study

First published: 14/10/2021

Last updated: 27/06/2024

Study Finalised

Administrative details

EU PAS number

EUPAS43687

Study ID

49257

DARWIN EU® study

No

Study countries

United Kingdom

Study description

Background/Rationale: A very rare syndrome of thrombosis associated with low platelets has been reported in a few cases of recent exposure to COVID-19 vaccine. This thrombotic thrombocytopenia syndrome seems to be affecting patients of all ages and both genders, at present there is no clear signal of risk factors.

Objectives: To evaluate an association between COVID-19 vaccine exposure and thromboembolic events occurring with thrombocytopenia (thrombotic thrombocytopenia syndrome, TTS).

Study design: Two primary study designs will be considered, a case control study and a self-controlled case series (SCCS). A cohort analysis will be considered, in addition or as an alternative to either of the primary study designs, pending feasibility assessment of the follow-up time.

Data Source(s): Data for the study will be accessed through the NHS Digital Trusted Research Environment (TRE), providing national data coverage. Primary care data will be linked with vaccination, hospitalization, COVID-19 test results, mortality data. Initial exploratory analyses will be conducted using the Oxford-Royal College of General Practitioners sentinel network, ORCHID network database (N>15million). Subjects of interest are people who have received a COVID-19 vaccine. However, we will require access to data from all subjects in the databases.

Study status

Finalised

Research institutions and networks

Institutions

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Simon de Lusignan

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 14/06/2021

Study start date
Planned: 15/03/2023

Actual: 01/03/2022

Data analysis start date
Planned: 03/04/2023

Actual: 07/06/2023

Date of final study report
Planned: 30/11/2023

Actual: 15/05/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

PASS Protocol Assoc D8111R00010 modified following SC_Redacted.pdf (9.04 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

D8111R00010

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To evaluate an association between COVID-19 vaccine exposure and thromboembolic events occurring with thrombocytopenia (thrombotic thrombocytopenia syndrome, TTS).

Study drug and medical condition

Medicinal product name, other

Vaxzevria

COVID-19 Vaccine (ChAdOx1-S [recombinant])

Anatomical Therapeutic Chemical (ATC) code

(J07BN02) covid-19, viral vector, non-replicating

covid-19, viral vector, non-replicating

Medical condition to be studied

COVID-19 immunisation

COVID-19

Additional medical condition(s)

COVID-19 vaccination/SARS-CoV-2 infection

Population studied

Age groups

- 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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

25428392

Study design details

Outcomes

Thrombotic thrombocytopenia syndrome, TTS

Data analysis plan

A detailed Statistical Analysis Plan (SAP) will be developed for this analysis. The SAP may modify the plans outlined in the protocol, any major modifications of primary endpoint definitions or their analyses would be reflected in a protocol amendment. All statistical analyses will use the R statistical software.

Documents

Study results

D8111R00010_Redacted_CSR_Synopsis-v3.pdf (141.35 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 source(s), other

- NHS Digital Trusted Research Environment. General Practice Extraction Service (GPES) Data for Pandemic Planning and Research (GDPPR), United Kingdom
- Oxford Royal College of General Practitioners Clinical Informatics Digital Hub (ORCHID), United Kingdom

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Data sources (types)

Administrative healthcare records (e.g., claims)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Case-control surveillance database

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