Epidemiology of thrombotic thrombocytopenia syndrome in integrated health-care database in England Secondary data analysis using a cohort design (Epidemiology of TTS)

First published: 24/03/2023

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Study Finalised

Administrative details

EU PAS number

EUPAS103927

Study ID

106282

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Objectives and Hypotheses: The overall objective is to estimate event rates and describe characteristics of patients with a record for Thrombotic thrombocytopenia syndrome (TTS), thromboembolism (TE), or thrombocytopenia (TCP), in the general population of England. Data Source(s): This is a retrospective cohort study using linked secondary databases in England accessed through the Oxford Royal College of General Practitioners Clinical Informatics Digital Hub (ORCHID), linked to nationwide data containing COVID data including diagnosis, polymerase chain reaction tests and vaccinations. ORCHID has contemporary data from > 17 million with good historic data from 40% of practices. Study Population: All patients, who are present in the integrated health records of ORCHID database at the start of each study period (Pre-COVID cohort: 01 January 2011 to 31 December 2019, COVID cohort: 01 July 2020 to 31 December 2020 and COVID vaccination cohort 01 January 2021 until 4 July 2022). Variables: The study outcome TTS is defined as a TE with TCP with an interval of 7 days before or after the TE diagnosis. Covariates include: Demographics, socioeconomics, medical history and risk factors for thrombosis and/or thrombocytopenia. Statistical Analysis: Unadjusted incidence rates of TCP, TE, and TTS will be calculated with associated Poisson exact 95% confidence intervals (CI) by dividing the number of incident events by the person-time at risk (presented per 100,000 person years). Logistic regression analysis will be used to assess the association between covariates and TTS, by calculating odds ratios (OR) with 95% CI.

Study status

Finalised

Research institutions and networks

Institutions

Nuffield department of Primary Care Health Sciences,University Of Oxford

Contact details

Study institution contact

Clinical Study Information Center AstraZeneca

information.center@astrazeneca.com

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

Actual: 01/03/2022

Data analysis start date

Actual: 24/01/2023

Date of final study report
Planned: 31/05/2023

Actual: 28/06/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AstraZeneca

Study protocol

d8111r00011-pass-csp-v4__Redacted.pdf(5.84 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

D8111R00011

Methodological aspects

Study type

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The overall objective is to estimate event rates and describe characteristics of patients with a record for TTS, thromboembolism, or thrombocytopenia, in the general population of England.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Medical condition to be studied

Thrombosis with thrombocytopenia syndrome

Population studied

Short description of the study population

The study population comprised of patients aged 16 years or older diagnosed with thrombocytopenia, thrombotic thrombocytopenia, and thromboembolism identified from the integrated databases in England.
Inclusion criteria:
- A minimum of 12 months medical history prior to the start of the study period

Exclusion criteria:
- Less than 12 months of prior history at start of each perspective study period.

Age groups

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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

9000000

Study design details

Outcomes

Thrombotic thrombocytopenia syndrome, thromboembolism or thrombocytopenia

Data analysis plan

Unadjusted incidence rates of TCP, TE, and TTS will be calculated with associated Poisson exact 95% confidence intervals (CI) by dividing the number of incident events by the person-time at risk (presented per 100,000 person years). Logistic regression analysis will be used to assess the association between covariates and TTS, by calculating odds ratios (OR) with 95% CI.

Documents

Study results

TTS_CSR_Synopsis__Redacted_(002)-v1.pdf(137.71 KB)

Data management

Data sources

Data source(s)

Hospital Episode Statistics

Data source(s), other

Oxford Royal College of General Practitioners Clinical Informatics Digital Hub (ORCHID) United Kingdom, Second Generation Surveillance System (SGSS) United Kingdom, National Immunisation Management System (NIMS) United Kingdom, Office of National Statistics (ONS) mortality data United Kingdom

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Oxford Royal College of General Practitioners Clinical Informatics Digital Hub (ORCHID), linked to nationwide data

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