French Adult primary Immune Thrombocytopenia: a pHarmacoepidemiological study (FAITH)

First published: 23/09/2013

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/28050

EU PAS number

EUPAS4574

Study ID

28050

DARWIN EU® study

No

Study countries

☐ France

Study description

Primary immune thrombocytopenia (ITP) is rare. First-line treatment is corticotherapy. Then, several second-line treatments (SLT) are available: splenectomy, off-label rituximab and thrombopoietin-receptor agonists since 2009. The compared efficacy and safety on clinical events in the long-term are unknown. The main objective of the FAITH study is to build the cohort of all treated adult persistent (≥3 months) primary ITP patients in France, to assess the benefit-to-risk ratio of SLT in real-life practice. Data source is the database of French Health Insurance System (SNIIRAM) which covers the entire French population. It collects demographic, chronic disease, hospitalization and drug dispensing data. All patients with ITP were extracted from 2009 to 2012, and then every year for 10 years. We will build the cohort from raw data. Outcomes (death, hospitalization, drug dispensing) will be compared according to SLT, with controls from the general population and untreated patients.

Study status

Ongoing

Research institutions and networks

Institutions

University Toulouse III

France

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Institution | Educational Institution

INSERM 1027

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Maryse Lapeyre-Mestre

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/10/2013

Actual: 15/10/2013

Study start date

Planned: 15/10/2013

Actual: 15/10/2013

Data analysis start date

Planned: 15/10/2013

Actual: 15/10/2013

Date of interim report, if expected
Planned: 01/05/2015

Actual: 10/10/2014

Date of final study report
Planned: 01/05/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

University of Toulouse

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

To build a national cohort of adult incident persistent or chronic primary ITP patients to describe exposure to available second-line treatments (in 2013, splenectomy, rituximab and TPO-RA).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

RITUXIMAB

ELTROMBOPAG

ROMIPLOSTIM

Medical condition to be studied

Immune thrombocytopenia

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)

Estimated number of subjects

10000

Study design details

Outcomes

Delivered data are raw. We will constitute the cohort as follows: 1) exclusion of probable erroneous codes, 2) exclusion of secondary ITP, 3) definition of diagnosis date through drug dispensing, 4) restriction to incident patients, 5) restriction to adults (≥18 years), 6) restriction to persistent or chronic ITP, 7) definition of index date (first persistent ITP treatment). Mortality: the date of death is indicated in the SNIIRAM.Efficacy outcomes: hospitalization for bleeding, ITP drug withdrawal, non-introduction of a new treatment for ITP, cumulative dose of corticosteroids.Safety outcomes: infections (hospitalizations or antibiotics dispensing), hospitalizations for cardio-vascular and venous thrombo-embolic events, cancers (including hematological).

Data analysis plan

Exposure to drugs will be calculated with Defined Daily Doses when applicable. For outcome occurrence assesment, Cox models will be performed. Time-varying analyses will be used to assess drug exposure.

Documents

Study publications

Moulis, Guillaume. Pharmacoépidémiologie de la thrombopénie immunologique en Fr…

Moulis G, Lapeyre-Mestre M, Mahévas M, Montastruc JL, Sailler L. Need for animp…

Moulis G, Lapeyre-Mestre M, Montastruc JL, Sailler L. Exposure tonon-corticoste…

Moulis G, Lapeyre-Mestre M, Palmaro A, Sailler L. Infections in non-splenectomi…

Moulis G, Palmaro A, Sailler L, Lapeyre-Mestre M. Corticosteroid Risk Function …

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

signed declaration of interest.pdf(509.87 KB)

Signed code of conduct

2013-0019-Declaration on compliance with the CoC-SDPP-4574.pdf(37.9 KB)

Signed code of conduct checklist

2013-0019-Checklist for CoC-SDPP-4574.pdf(634.06 KB)

Signed checklist for study protocols

2013-0019-Checklist for Study Protocols-SDPP-4574.pdf(241.43 KB)

Data sources

Data source(s), other

SNNIR-AM France

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription 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