A Post-Marketing Safety Study to Evaluate the Occurrence of Aseptic Meningitis Syndrome (AMS) in an Adult Population (>= 18 Years) Treated with Doses of >= 1g/kg Intragam® 10 NF

First published: 28/02/2017

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Study Ongoing

Administrative details

EU PAS number

EUPAS17881

Study ID

20904

DARWIN EU® study

No

Study countries

☐ Australia

Study description

This is a prospective observational study in patients treated with Intragam 10 NF. Patients who are naïve to IVIg (Intravenous immunoglobulin) or who change to Intragam 10 NF from an alternative immunoglobulin product will be invited to participate in the study. Study participants will be required to report any adverse events of AMS, migraine and severe headache during their infusion, during their treatment course, or within 7 days of their last infusion, to the treatment centre.

Study status

Ongoing

Research institutions and networks

Institutions

CSL Behring

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Institution

Gold Coast Hospital Southport, Australia, Royal Melbourne Hospital Parkville, Australia, Royal Adelaide Hospital Adelaide, Australia, Concord Repatriation General Hospital Concord, Australia,

Canberra Hospital Canberra, Australia, Hollywood Private Hospital Nedlands WA

Contact details

Study institution contact

Trial Registration Coordinator clinicaltrials@cslbehring.com

Study contact

clinicaltrials@cslbehring.com

Primary lead investigator

Trial Registration Coordinator

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/08/2016

Actual: 31/08/2016

Study start date

Planned: 01/03/2017

Actual: 03/04/2017

Date of final study report

Planned: 30/06/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

CSL Limited

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

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 the occurrence of AMS cases in an adult population (>= 18 years of age) treated with doses of >= 1g/kg Intragam 10 NF.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective observational study design

Study drug and medical condition

Medical condition to be studied

Meningitis aseptic

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

Immunocompromised

Estimated number of subjects

200

Study design details

Outcomes

Confirmed or probable AMS in patients during treatment or within 7 days of the last dose of Intragam 10 NF (>= 1g/kg). Migraine and severe headache in patients during treatment or within 7 days of the last dose of Intragam 10 NF (>= 1g/kg).

Data analysis plan

Descriptive statistics will be used to evaluate the occurrence of cases of AMS, severe headache and migraine in an adult population (>= 18 years of age) treated with doses of >= 1g/kg Intragam 10 NF. Generalised Linear regression methodology (e.g. logistic regression) will be adopted to evaluate the risk factors associated with confirmed or probable AMS occurring before or during treatment with doses of >= 1g/kg Intragam 10 NF.

Data management

Data sources

Data sources (types)

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