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

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## Administrative details

<b>EU PAS number</b> EUPAS17881	
LOTAS17001	
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

### **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)** 

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