Drug Utilization Study on the Risk Minimisation Tools for Sialanar

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Study Planned

Administrative details

EU PAS number

EUPAS24635

Study ID

24636

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ United Kingdom

Study status

Planned

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Katherine Martin

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 28/12/2017

Actual: 28/12/2017

Study start date

Planned: 01/01/2018

Data analysis start date

Planned: 01/12/2021

Date of final study report

Planned: 01/02/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Proveca Ltd

Study protocol

Sialanar DUS PRO_GLY_004 v5.0 20180321.pdf(428 KB)

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)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

The primary objective is to monitor and assess effectiveness of the educational materials helping carers to adjust dose titration in response to identified anticholinergic side effects

Study drug and medical condition

Name of medicine

SIALANAR

Medical condition to be studied

Drooling

Population studied

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Estimated number of subjects

500

Study design details

Outcomes

Incidence of anticholinergic side effects resulting in treatment dose change or cessation of Sialanar, The number of anticholinergic adverse events brought to the attention of the prescribing physician (initiator – e.g. consultant neurologist) by the carer that occurs in between the routine consultation time interval. The number of occasions and reasons Sialanar treatment is stopped due to anticholinergic adverse events. Quantify the frequency of off-label use of Sialanar

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Data analysis plan

Descriptive statistics will be used. The analysis will be performed per country if possible and for all countries combined (if possible for same data categories). Demographic characteristics and Sialanar treatment outcomes will be summarised according to diagnosis (if possible and sufficient numbers).

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