International Cooperative Growth Study Post Marketing Surveillance Program For Nutropin Aq® [Somatropin (rDNA Origin) Injection] (iNCGS)

First published: 13/11/2014

Last updated: 01/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS7948

Study ID

30502

DARWIN EU® study

No

Study countries

Austria

France

Germany

Italy

Romania

Spain

United Kingdom

Study description

The objective of this study is to collect long term safety and efficacy information on Ipsen’s growth hormone (GH) NutropinAq® during treatment of pediatric growth disorders for which GH is indicated. International multicenter, open label, observational, post-marketing surveillance study, duration open ended, patients participation: until fusion of the epiphyses (end of growth period). Patients initiating therapy or currently receiving therapy with NutropinAq® for paediatric growth disorders and meeting eligibility criteria will be proposed to enter in the registry. The aim is to recruit as many patients as possible in the participating sites to obtain a sample that is representative of the treated population. Inclusion criteria:Patients must meet the following criteria:• Children of either sex who are initiating therapy or currently receiving therapy with NutropinAq® for the treatment of growth failure • Written informed consent signed by both parents or by the liable parent or by the legal guardian when applicable, and by the child when applicable• Patients who are willing to comply with follow up appointments throughout study participation.

Study status

Finalised

Research institutions and networks

Institutions

Ipsen Pharma

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Institution

Multiple centres: 158 centres are involved in the study

Contact details

Study institution contact

Ipsen Medical Director clinical.trials@ipsen.com

Study contact

clinical.trials@ipsen.com

Primary lead investigator

Ipsen Medical Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2006

Actual: 01/06/2006

Study start date
Planned: 01/06/2006

Actual: 01/06/2006

Date of interim report, if expected
Planned: 14/06/2016

Actual: 14/06/2016

Date of final study report
Planned: 31/12/2017

Actual: 22/12/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

IPSEN Pharma

Study protocol

2-79-58035-005-protocol-20140715_Redacted.pdf (5.28 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The objective of this non-interventional study is to collect long term safety and efficacy information on Ipsen's growth hormone (GH) NutropinAq® regarding treatment of paediatric growth disorders for which Growth Hormone is indicated.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective and restrospective observational study, Post-marketing surveillance study

Study drug and medical condition

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

SOMATROPIN

Medical condition to be studied

Growth hormone deficiency

Population studied

Short description of the study population

Boys and girls being treated with NutropinAq® for paediatric growth disorders for which growth hormone (GH) is indicated.

Patients must meet the following criteria to be eligible for study admission:
1. Children of either sex who are initiating therapy or currently receiving therapy with NutropinAq® for the treatment of growth failure,
2. Written informed consent signed by both parents or by the liable parent or by the legal guardian when applicable, and by the child when applicable,
3. Patients who are willing to comply with follow-up appointments throughout study participation.

Age groups

- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

Estimated number of subjects

3.660

Study design details

Data analysis plan

• Height, BMI and Weight SDS computation • Height velocity computation• Descriptive statistics for baseline demographics variables, disease history and aetiology, treatment compliance, Nutropin administration, growth hormone previous treatment, medical history and adverse events• Auxological data summary and change from baseline in auxological data• Analyses will be performed by etiology and by country

Documents

Study results

2-79-58035-005-synopsis_No redactions.pdf (4.38 MB)

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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

Unknown