Follow-up of adult patients treated with growth hormone NUTROPIN Aq® (Nutropin in Adults)

First published: 13/11/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7944

Study ID

30183

DARWIN EU® study

No

Study countries

☐ France

Study description

The objectives of this observational study are: - Define the profile of patients treated with NutropinAq® and describe the conditions for initiation and follow-up of treatment - Assess the safety of NutropinAq® in adults - Collect data on the quality of life of adults treated with NutropinAq®.

Study status

Finalised

Research institutions and networks

Institutions

Ipsen Pharma

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Institution

Multiple centres: 55 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: 01/02/2005

Actual: 01/02/2005

Study start date

Planned: 12/04/2005

Actual: 12/04/2005

Data analysis start date

Planned: 29/12/2009

Actual: 29/12/2009

Date of final study report

Planned: 30/06/2014

Actual: 07/07/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Ipsen Pharma

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

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

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The objectives of this observational study are: - Define the profile of patients treated with NutropinAq® and describe the conditions for initiation and follow-up of treatment - Assess the safety of NutropinAq® in adults - Collect data on the quality of life of adults treated with NutropinAq®.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational Model :Case-only

Study drug and medical condition

Name of medicine

NUTROPINAQ

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

SOMATROPIN

Anatomical Therapeutic Chemical (ATC) code

(H01AC01) somatropin

somatropin

Additional medical condition(s)

Somatotrope deficit

Population studied

Short description of the study population

Adult patients treated with growth hormone NUTROPIN Aq®.

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

205

Study design details

Outcomes

Profile of patients treated with NutropinAq® and conditions for initiation and follow-up of treatment, Safety of NutropinAq® in adults. Quality of life of adults treated with NutropinAq®.

Data analysis plan

Descriptive analysis of all collected data at the baseline and follow-up visits according a statistical plan validated by authorities

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

Unknown