An Observational, Multicentre, Open label, Post-Marketing Surveillance Program to assess the long-term safety and efficacy of Somatuline® Autogel® in the treatment of acromegaly when administered by patients or their partners (“Home Injection Group”) or administered by Healthcare Professionals

First published: 22/05/2020

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS35337

Study ID

35338

DARWIN EU® study

No

Study countries

Australia

Study description

Objective: To assess the safety and local tolerability of the long-term use of Somatuline Autogel when administered by patients or their partners (“Home Injection Group”) and the safety and local tolerability inpatients receiving their injection from a healthcare professional (HCP) (“Reference Group”).

Study status

Finalised

Research institutions and networks

Institutions

Ipsen Pharma

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 5 centres are involved in the study

Contact details

Study institution contact

Medical Director clinical.trials@ipsen.com

Study contact

clinical.trials@ipsen.com

Primary lead investigator

Medical Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/08/2013

Study start date

Planned: 12/08/2008

Actual: 14/04/2009

Data analysis start date

Planned: 12/10/2012

Actual: 04/05/2013

Date of final study report

Planned: 04/01/2015

Actual: 04/01/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Ipsen

Study protocol

a9b52030219-protocol.pdf (4.46 MB)

Regulatory

Was the study required by a regulatory body?

No

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:

Combined primary data collection and secondary use of data

Main study objective:

To assess the safety and local tolerability of the long-term use of Somatuline Autogel when administered by patients or their partners.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post-marketing surveillance programme

Study drug and medical condition

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

LANREOTIDE ACETATE

Anatomical Therapeutic Chemical (ATC) code

(H01CB03) lanreotide

lanreotide

Medical condition to be studied

Acromegaly

Population studied

Short description of the study population

Approximately 30 patients who are established on treatment with Somatuline Autogel for acromegaly. All eligible patients at participating centres can enrol in this PMS programme if both they and the clinical staff are willing to do so. Patients MUST satisfy all of the following entry criteria in order to be enrolled in this PMS programme.

Inclusion Criteria:

For all patients:

1. The patient must give written (personally signed and dated) informed consent for their data to be included in the database for this PMS programme and any subsequent analysis.
2. The patient must have been receiving treatment with Somatuline Autogel at a stable dose for at least 4 months.
3. The patient must have a diagnosis of acromegaly.
4. The patient must be at least 18 years of age.

For patients receiving or intending to receive Somatuline Autogel by home injection:

5. The patient must be able to store Somatuline Autogel safely in a refrigerator in their own home and either collect it from their GP/Pharmacy on a monthly basis, or receive the medication by a home delivery service.

Exclusion Criteria:

For all patients:

1. The patient is pregnant or breast-feeding, unless continued treatment with Somatuline Autogel is clearly needed (as determined by the treating clinician).

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

Other

Special population of interest, other

Acromegaly patients

Estimated number of subjects

38

Study design details

Outcomes

To assess the long-term safety following parameters will be evaluated: Incidence of adverse events (AEs) and serious adverse events (SAEs), Concomitant medications / therapies / surgical procedures. The incidence of local injection site tolerability through patient reported comments, The efficacy endpoints: GH plasma levels, IGF-1 plasma levels, Tumour size, Acromegaly symptoms.

Data analysis plan

As this is an observational program no formal statistical analysis will be performed, and therefore no sample size calculation has been conducted. All data will be summarised descriptively by administration group and/or by dose and injection interval as appropriate.

Documents

Study results

a9b52030219-synopsis.pdf (2.27 MB)

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)

Electronic healthcare records (EHR)

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