An Observational, Multicentre, Open Label, Non Interventional Programme 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 (Somatuline ACRO PMS 213 study)

First published: 20/11/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/30180

EU PAS number

EUPAS7982

Study ID

30180

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

The purpose of this study, is 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 in patients 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: 7 centres are involved in the study

Contact details

Study institution contact

Medical Director, Endocrinology

Study contact

clinical.trials@ipsen.com

Primary lead investigator

Medical Director, Endocrinology

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 26/04/2008

Actual: 26/04/2008

Study start date

Planned: 11/09/2008

Actual: 11/11/2008

Date of final study report

Planned: 17/12/2014

Actual: 12/02/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Ipsen Ltd.

Study protocol

Y-97-52030-213 v1.2_Redacted.pdf(279.85 KB)

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:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The purpose of this study, is 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 in patients receiving their injection from a healthcare professional (HCP) ("Reference Group").

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post-marketing surveillance programme

Study drug and medical condition

Medical condition to be studied

Acromegaly

Population studied

Short description of the study population

Patients who were established on treatment with Somatuline Autogel for acromegaly.

Patients must satisfy all of the following entry criteria in order to be enrolled in this PMS programme:

For all patients:

• 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.

• The patient must have been receiving treatment with Somatuline Autogel at a stable dose for at least 4 months.

• The patient must have a diagnosis of acromegaly.

• The patient must be at least 18 years of age.

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

• 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.

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

50

Study design details

Outcomes

Safety and local tolerability of Somatuline Autogel when administered by patients or their partners or from a healthcare professional, -Efficacy of Somatuline Autogel in both groups -Training requirements for patients / partners to perform home injection of Somatuline Autogel -Acceptability of home injections to patients, partners and healthcare professionals

Data analysis plan

As this is an observational programme 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

Y-97-52030-213_synopsis_Redacted.pdf(2.27 MB)

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