An observational, multicentre, open label, non-interventional programme to assess the long-term safety and efficacy of Somatuline® Autogel® in the treatment ofneuroendocrine tumours 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

EUPAS35332

Study ID

35497

DARWIN EU® study

No

Study countries

☐ Australia

Study description

Objective: to assess the long-term safety, tolerability and efficacy of home injections with injections administered by a healthcare professional in patients with neuroendocrine tumours, over a period of 2-4 years and to evaluate the acceptability of home injections to patients, partners and HCPs.

Study status

Finalised

Research institutions and networks

Institutions

Ipsen Pharma

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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: 05/08/2009

Actual: 05/08/2009

Data analysis start date

Planned: 17/12/2013

Actual: 17/12/2013

Date of final study report

Planned: 18/04/2015

Actual: 18/04/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Ipsen

Study protocol

a9b52030220-protocol.pdf(4.47 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

Study Design

Non-interventional study design

Cohort

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

Neuroendocrine tumour

Population studied

Short description of the study population

All patients must fulfil the following:

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 data analysis.

2) The patient must have been receiving treatment with Somatuline Autogel at a stable dose and frequency for at least 4 months.

3) The patient must have a diagnosis of NET.

4) The patient must be at least 18 years of age.

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

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

Exclusion Criteria

Patients will not be included in the programme if:

• 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

Neuroendocrine tumour (NET) patients

Estimated number of subjects

25

Study design details

Outcomes

The following data will be evaluated in order to assess the long-term safety: incidence of adverse events (AEs) and serious adverse events (SAEs) considered to be related to Somatuline Autogel in both groups, concomitant medications / therapies / surgical procedures, the incidence of local injection site tolerability. The long-term efficacy of Somatuline Autogel when administered by home-injection will be compared to the efficacy following administration by a HCP 24 hrs 5-HIAA urine levels, Tumour size, NET symptoms.

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

a9b52030220-synopsis.pdf(2.27 MB)

Data management

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