An Observational, multicentre, open label, non interventional programme to assess the long-term safety and efficacy of Somatuline® Autogel® in the treatment of neuroendocrine tumours when administered by patients or their partners (“Home Injection Group”) or administered by Healthcare Professionals (Somatuline NET PMS 215 study)

First published: 20/11/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7986

Study ID

30177

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

A two year observational study wherein enrolled patients have a diagnosis of NET and have been established on a stable dose of Somatuline Autogel for at least 4 months before entering the programme. The dose and interval between injections will have been determined by the treating clinician in accordance with usual clinical practice. Patients enrolled in this PMS programme may receive their injections from a HCP, or by home injection. Patients receiving home injections will enter the “Home Injection Group”. Patients receiving their injections from a Healthcare Professional (HCP) will form a “Reference Group”. The number of patients enrolled into each group is not mandated

Study status

Finalised

Research institutions and networks

Institutions

Ipsen Pharma

First published: 01/02/2024

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Institution

Multiple centres: 7 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

Medical Director, Endocrinology

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/09/2008

Actual: 29/09/2008

Study start date

Planned: 02/03/2009

Actual: 02/03/2009

Date of final study report

Planned: 23/12/2014

Actual: 18/02/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Ipsen Ltd

Study protocol

Y-97-52030-215 v1.2 15Oct12_Redacted.pdf(247.34 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:

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

Neuroendocrine tumour

Population studied

Short description of the study population

Patients (of either sex), who were 18 years of age or above, and who were established on treatment with Somatuline Autogel for NET were enrolled within the 2 year recruitment period, and were remained in the Post Marketing Surveillance (PMS) programme for at least 2 years.

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.

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 patients

Estimated number of subjects

50

Study design details

Outcomes

Evaluation of incidence of related adverse events and use of concomitant medications in the home injection versus the reference group.

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 is summarized descriptively by administration group and by does and injection interval as appropriate.

Documents

Study results

Y-97-52030-215_synopsis-no redactions.pdf(2.26 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)

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