

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

### **PURI**

<https://redirect.ema.europa.eu/resource/35338>

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### **EU PAS number**

EUPAS35337

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### **Study ID**

35338

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## DARWIN EU® study

No

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### Study countries

Australia

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### 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”).

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### 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

Study contact

[clinical.trials@ipsen.com](mailto:clinical.trials@ipsen.com)

### Primary lead investigator

Medical Director

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 01/08/2013

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### Study start date

Planned: 12/08/2008

Actual: 14/04/2009

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### Data analysis start date

Planned: 12/10/2012

Actual: 04/05/2013

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### 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

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### **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

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**Study type:**

Non-interventional study

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**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

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**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

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**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

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## **Anatomical Therapeutic Chemical (ATC) code**

(H01CB03) lanreotide

lanreotide

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## **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).
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### **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)

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### **Special population of interest**

Other

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### **Special population of interest, other**

Acromegaly patients

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### **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.

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### **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)

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## Data management

### Data sources

#### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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#### **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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

No