

# Global Patient Registry to Monitor Long-term Safety and Effectiveness of Increlex® in Children and Adolescents With Severe Primary Insulin-like Growth Factor-1 Deficiency (SPIGFD)

**First published:** 17/10/2014

**Last updated:** 23/01/2026

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS7708

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### Study ID

50235


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### DARWIN EU® study

No

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### Study countries

 Austria


 France

 Germany

 Italy

 Poland

 Spain

 Sweden

 United Kingdom

 United States

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## **Study description**

The Increlex® Global Registry is a descriptive, multicenter, observational, prospective, open-ended, non interventional, post-authorisation surveillance registry.

This registry is a Post-Authorisation Safety Study which is intended primarily to collect, analyse and report safety data during and up to at least 5 years after the end of treatment in children and adolescents receiving Increlex® therapy for Severe Primary IGF-1 Deficiency according to the locally approved product information.

The second objective is to follow the effectiveness of this treatment. Patients who have already started Increlex® therapy before entering this registry may be included and data will be collected retrospectively.

For each subject, the Increlex® treatment period duration is at the discretion of the investigator according to his/her judgment on the basis of clinical needs of the subject.

The Sponsor will attempt to follow the subject until the Final adult height is attained if not reached within the 5 years post treatment period. Safety data analyses are performed every 6 months. In addition, an independent Data Monitoring Committee (DMC) composed of 3 experts in paediatric endocrinology, oncology and statistician are conducting a review of available safety data on at least an annual basis.

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## **Study status**

Ongoing

## Research institutions and networks

### Institutions

Esteve Pharmaceuticals, S.A.

### Contact details

#### Study institution contact

Global Clinical Development Department

[increlexregistry@esteve.com](mailto:increlexregistry@esteve.com)

Study contact

[increlexregistry@esteve.com](mailto:increlexregistry@esteve.com)

#### Primary lead investigator

Adelaida Morte

Primary lead investigator

### Study timelines

#### Date when funding contract was signed

Planned: 19/06/2008

Actual: 19/06/2008

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#### Study start date

Planned: 01/01/2009

Actual: 09/12/2008

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### **Data analysis start date**

Planned: 01/12/2010

Actual: 01/12/2010

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### **Date of interim report, if expected**

Planned: 31/12/2025

Actual: 15/12/2025

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### **Date of final study report**

Planned: 31/12/2028

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Esteve Pharmaceuticals, S.A.

## Study protocol

[2-79-52800-002\\_Protocol Version 10 Including Amendment 9\\_Final](#)

[Redacted\\_18Sep25.pdf](#) (949.09 KB)

[2-79-52800-002\\_Protocol Amendment 8\\_Final Redacted\\_08Feb22 \(3\).pdf](#) (6.17 MB)

## Regulatory

## Was the study required by a regulatory body?

Yes

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## Is the study required by a Risk Management Plan (RMP)?

EU RMP category 2 (specific obligation of marketing authorisation)

## Other study registration identification numbers and links

NCT00903110

[Link to ClinicalTrials.gov](#)

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

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

Effectiveness study (incl. comparative)

**Main study objective:**

To collect, analyse and report safety data during and at least 5 years after the end of the treatment in children and adolescents receiving Increlex therapy for SPIGFD according to the locally approved product information.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Observational Model: Case-Only

## Study drug and medical condition

**Medicinal product name**

INCRELEX

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

MECASERMIN

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**Anatomical Therapeutic Chemical (ATC) code**

(H01AC03) mecasermin

mecasermin

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**Medical condition to be studied**

Severe primary insulin like growth factor-1 deficiency

Growth failure

## Population studied

## Age groups

- Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
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## Estimated number of subjects

500

# Study design details

## Outcomes

Incidence of: serious adverse events (SAEs) including any AESI of neoplasia, all targeted adverse events (AEs), all AEs, deaths and withdrawals due to AEs during Increlex® treatment period up to 30 days after the last dose. Changes from baseline for effectiveness variables, Estimation of difference between predicted & final adult height, Modelling effectiveness parameters, Dose administered & duration of exposure, Biological assessments, genetic tests, Incidence of safety events at 2 and 5 years post-treatment, Description of neoplasias (benign and malignant) and hypoglycaemias, Evolution of QoL using EQ-5D-Y.

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## Data analysis plan

The statistical analyses will be performed in accordance with ICH E9 guideline and will be based on the pooled data from the individual study sites, unless otherwise stated.

Primary analyses during treatment period:

- description and incidence of any serious adverse events including neoplasia,
- incidence of all targeted adverse events
- description and incidence of all adverse events.

## Documents

## Study report

[2-79-52800-002\\_synopsis\\_07Jan2022\\_no marks \(2\).pdf](#) (2.73 MB)

[2-79-52800-002\\_synopsis\\_01Dec2011.pdf](#) (477.98 KB)

[2-79-52800-002\\_synopsis\\_10Jan2020.pdf](#) (2.77 MB)

[2-79-52800-002\\_synopsis\\_14Dec2015.pdf](#) (2.28 MB)

[2-79-52800-002\\_synopsis\\_20Dec2017.pdf](#) (2.66 MB)

[2-79-52800-002\\_synopsis\\_22Nov2013.pdf](#) (119.03 KB)

[2-79-52800-002\\_CSR Synopsis\\_06Dec23\\_No Redaction Marks\\_Final.pdf](#) (2.74 MB)

## Study publications

[Bang P, Polak M, Woelfle J, Houchard A, EU IGFD Registry Study Group.](#)

[Effective...](#)

[Bang P, Woelfle J, Perrot V, Sert C, Polak M. Effectiveness and safety of rhIGF...](#)

[Bang P, Polak M, Perrot V, Sert C, Shaikh H, Woelfle J. Pubertal Timing and Gro...](#)

[Bang P, Polak M, Bossowski A, Maghnie M, Argente J, Ramon-Krauel M, Sert C, Per...](#)

[Ramon-Krauel M, Polak M, Maghnie M, Woelfle J, Sert C, Perrot V, Bang P. Near-A...](#)

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## 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

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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