

# GH-4831: CROITRE Registry :French registry of children treated with Norditropin® for short stature associated with Noonan Syndrome

**First published:** 16/03/2022

**Last updated:** 14/03/2024

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS46223

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### Study ID

46845

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### DARWIN EU® study

No

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### Study countries

 France

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### Study description

This is a non-interventional registry of children treated with Norditropin® for short stature due to Noonan Syndrome (NS). This study aims to provide data on long-term growth evolution and safety of Norditropin® as well as Health Related Quality of Life (HRQoL) data. This registry will include the entirety of children treated with Norditropin® for short stature due to NS over the inclusion period. The decision to initiate treatment with commercially available Norditropin® is made by the patient/parents/Legally Acceptable Representative (LAR) and the treating physician before and independently from the decision to include the patient in this study.

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### **Study status**

Ongoing

## Research institutions and networks

### Institutions

#### [Novo Nordisk](#)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

**Institution**

#### [CHU de Toulouse - Hôpital des Enfants](#)

**First published:** 01/02/2024

**Last updated:** 01/02/2024

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Leclerc, LE KREMLIN-BICETRE, Hôpital des Enfants  
Hôpital des Enfants 330 avenue de Grande-  
Bretagne, Toulouse cedex 9

## Contact details

### Study institution contact

Clinical Transparency (dept. 2834) Novo Nordisk A/S  
pactadmin@novonordisk.com

Study contact

[pactadmin@novonordisk.com](mailto:pactadmin@novonordisk.com)

### Primary lead investigator

Clinical Transparency (dept. 2834) Novo Nordisk A/S

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 21/02/2022

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**Study start date**

Planned: 16/03/2022

Actual: 16/03/2022

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**Date of final study report**

Planned: 17/03/2029

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Novo Nordisk A/S

## Study protocol

[4831 protocol eu-pas-reg redacted.pdf](#) (937.68 KB)

## 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 3 (required)

## Other study registration identification numbers and links

## Methodological aspects

### Study type

#### Study type list

**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Main study objective:**

The primary objective is to describe the long-term change of height in children treated with Norditropin® for short stature due to NS over a 4-year period in routine clinical practice in France.

### Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Prospective and retrospective design

### Study drug and medical condition

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

SOMATROPIN

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### **Medical condition to be studied**

Noonan syndrome

## Population studied

### **Age groups**

- Adolescents (12 to < 18 years)
  - Children (2 to < 12 years)
  - Infants and toddlers (28 days - 23 months)
  - Preterm newborn infants (0 - 27 days)
  - Term newborn infants (0 - 27 days)
  - 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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### **Estimated number of subjects**

221

## Study design details

### **Outcomes**

Change in height standard deviation score, According to study protocol section 8.1.1.2

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## Data analysis plan

The following statistics will be provided for quantitative variables: number of patients with non-missing and missing values, mean, standard deviation, median, first quartile (Q1), third quartile (Q3), minimum and maximum value, mode (for discrete quantitative variables with limited variability). For qualitative variables, the number and proportion of each variable modality will be provided together with the number of missing values. Proportions will be computed based on the population with non-missing data. Missing data will not be imputed or replaced. A descriptive analysis will be conducted on all study endpoints for which data has been collected both on FAS (GAS for primary endpoint) and per subgroups of interest as long as that the sizes of the subgroups are relevant for statistical estimations.

## 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](#)

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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