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

Study ID

46845

DARWIN EU® study

No

Study countries

☐ France

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.

Study status

Ongoing

Research institutions and networks

Institutions

Novo Nordisk

First published: 01/02/2024

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Institution

CHU de Toulouse - Hôpital des Enfants

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Institution

HOPITAL DE BICETRE 78, avenue du Général 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

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

Study start date
Planned: 16/03/2022

Actual: 16/03/2022

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

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

EU RMP category 3 (required)

Other study registration identification numbers and links

UTN:U1111-1264-1805

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

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

Medical condition to be studied

Noonan syndrome

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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)

Estimated number of subjects

221

Study design details

Outcomes

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

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

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

No