NN8640-4787 A Non-interventional, Observational, Registry-based Study to Investigate Long-term Safety and Clinical Parameters of Somapacitan Treatment in Paediatric Patients With Growth Hormone Deficiency During Routine Clinical Practice

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000602

Study ID

1000000602

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] Saudi Arabia
- [ ] Slovenia
- [ ] United States

Study description

The aim of this study is to look at the long-term safety and clinical parameters of somapacitan in paediatric participants with growth hormone deficiency under routine clinical practice conditions. The study population will include at least 400 paediatric growth hormone deficient participants from the Global Registry for Novel Therapies in Rare Bone and Endocrine Conditions (GloBE-Reg) treated with once-weekly somapacitan and fulfilling the eligibility criteria of the study. The total duration of the study is planned to 10 years consisting of a 5-year recruitment period in the GLoBE-Reg followed by a 5-year follow-up period.

Study status

Ongoing

Research institutions and networks

Institutions

Novo Nordisk

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 13/09/2023

Study start date
Planned: 13/12/2024

Actual: 13/12/2024

Date of final study report
Planned: 20/09/2035

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk A/S

Study protocol

4787 protocol hma-ema redacted.pdf (1.01 MB)

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)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To investigate long-term safety of somapacitan treatment in paediatric patients with growth hormone deficiency (GHD) in the setting of routine clinical practice with special focus on neoplasms and type 2 diabetes mellitus (T2DM).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

SOGROYA

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

SOMAPACITAN

Anatomical Therapeutic Chemical (ATC) code

(H01AC07) somapacitan

somapacitan

Medical condition to be studied

Growth hormone deficiency

Neoplasm

Type 2 diabetes mellitus

Population studied

Short description of the study population

Paediatric participants with growth hormone deficiency.

Inclusion Criteria:

- Treated with commercially available somapacitan according to local practice at the discretion of the physician.
- Primary confirmed diagnosis of growth hormone deficiency as per local practice.
- Male or female below 18 years of age at the time of signing informed consent in the GLoBE-Reg.

Exclusion Criteria:

- Participants with active malignancy or in treatment for active pre-existing malignancy.

Age groups

- **Paediatric Population (< 18 years)**
  - Neonate
    - 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)

Estimated number of subjects

400

Study design details

Outcomes

Number of adverse drug reactions, Number of medication errors (incorrect dose administration), Number of participants with incident neoplasm, Number of participants with incident diabetes mellitus type 2, Height velocity, Change in height velocity standard deviation score (HVSDS), Change in height standard deviation score (HSDS), Change in insulin-like growth factor I (IGF-I) standard deviation score (SDS), Change in bone age (measured as years), Change in bone age (measured as months), Participants reaching near adult height, Change in height SDS in participants reaching near adult height.

Data analysis plan

No statistical comparison is planned due to limitations in the observational nature of the data collection.

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 source(s), other

Global Registry for Novel Therapies in Rare Bone and Endocrine Conditions (GloBE-Reg)

Data sources (types)

Disease registry

Drug prescriptions

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