NN8640-4515 A multi-national, multi-centre, prospective, single-arm, observational, non-interventional post-authorisation safety study to investigate long-term safety of Sogroya® (somapacitan) in adults with growth hormone deficiency (AGHD) under routine clinical practice

First published: 20/04/2023

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS104526

Study ID

105300

DARWIN EU® study

No

Study countries

- [ ] Australia
- [ ] Brazil
- [ ] Germany
- [ ] Saudi Arabia
- [ ] Slovenia
- [ ] United Kingdom
- [ ] United States

Study description

In this study, the general long-term safety and effectiveness of Sogroya (somapacitan) in adults with growth hormone deficiency (AGHD) being treated per normal clinical practice is looked into. In the study, information on side effects and how well Sogroya (somapacitan) works during long term treatment in people with Adult Growth Hormone Deficiency (AGHD) will be collected and analysed. Participants will be treated with Sogroya (somapacitan) as prescribed by the study doctor, in accordance with normal clinical practice. The study will last for 5-10 years, depending on when the participant join the study. The participant will be asked to complete two short questionnaires during every visit to the clinic. The questionnaires will collect information on the participant's well-being, work ability and ability to perform daily activities.

Study status

Ongoing

Research institutions and networks

Institutions

Novo Nordisk

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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

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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

Actual: 15/02/2022

Study start date

Actual: 03/02/2023

Date of final study report
Planned: 15/12/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novo Nordisk A/S

Study protocol

4515 16-1-01 protocol eu-pas-reg-redacted.pdf(1.08 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)

Other study registration identification numbers and links

U1111-1264-8642 NCT05718570

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

To investigate long-term safety of Sogroya® (somapacitan) therapy in patients with AGHD in the setting of routine clinical practice with special focus on neoplasms and diabetes mellitus type 2.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

SOMAPACITAN

Medical condition to be studied

Growth hormone deficiency

Additional medical condition(s)

Adults with growth hormone deficiency

Population studied

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)

Estimated number of subjects

400

Study design details

Outcomes

Number of Adverse drug reaction (ADRs) Incident Neoplasm Incident Diabetes Mellitus type 2, Number of Adverse Events (AEs) Number of Serious Adverse Events (SAEs) Number of Medication Errors (incorrect dose administration rate)

Data analysis plan

Frequencies of ADRs during the study period will be summarised by MedDRA SOC and PT. This summary is displayed with number and proportion of patients with at least one event, number of event and event rate (events per 100 patient-years of exposure). In addition, incidence rates will be calculated for the endpoints Neoplasm and Diabetes Mellitus type 2.

Documents

Study report

4515 regulatory pass progress report no. 1 eu-pas-reg redacted.pdf(387.35 KB)

4515 regulatory pass progress report no. 2 eu-pas-reg redacted.pdf(436.97 KB)

Study, other information

4515 regulatory pass progress report no. 2 eu-pas-reg redacted.pdf(436.97 KB)

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

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