Real-world experience of children with growth hormone deficiency who switched from daily growth hormone to the Long-Acting Growth Hormone Somatrogon

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000829

Study ID

1000000829

DARWIN EU® study

No

Study countries

Czechia

Israel

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Noya Machtiger-Azoulay

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 29/09/2025

Actual: 29/09/2025

Study start date

Planned: 27/02/2026

Actual: 17/02/2026

Date of final study report

Planned: 30/10/2026

Study protocol

C0311030_SWITCH NIS Protocol_11Dec2025 Clean_Redacted.pdf (391.9 KB)

C0311030_SWITCH NIS Protocol_V2.0_21 May2026_Redacted.pdf (426.16 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Other

Study topic, other:

Paediatric growth disorders/Growth Hormone Deficiency treatment in children

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

This is a multi-country, non-interventional, retrospective cohort study, utilizing structured data of patients up to 17 years old who switched from daily GH to weekly somatrogon, a long-acting hGH treatment, as prescribed by the treating physician according to routine clinical care

Main study objective:

Primary Objective:

• To evaluate and compare the growth hormone treatment effectiveness in participants who switched from daily growth hormone to weekly somatrogon.

Secondary Objectives:

• To evaluate and compare the safety profile of weekly somatrogon and daily somatropin in children with GHD

• To assess the proportion of patients that switched back to daily somatropin among
patients receiving somatrogon
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• To assess reasons for switch-back among patients who switched back from somatrogon to daily GH

• To evaluate and compare adherence to growth hormone treatment of participants before and after switching to somatrogon treatment.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

GENOTROPIN

NGENLA

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

SOMATROGON

SOMATROPIN

Anatomical Therapeutic Chemical (ATC) code

(H01AC08) somatrogon

somatrogon

(H01AC01) somatropin

somatropin

Medical condition to be studied

Growth hormone deficiency

Population studied

Short description of the study population

The target population consists of patients who transitioned from daily GH therapy to weekly somatrogon, a long-acting hGH treatment, as prescribed by their treating physician in routine clinical practice. The source population

includes patients from the Maccabi HCO database in Israel and the REPAR registry in the Czech Republic. Eligible patients are male or female, up to 17 years old at the start of the pre-index period, with at least 6 months of data on daily GH treatment (somatropin) and a minimum of 6 months of follow-up data after switching to long-acting somatrogon.

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

450

Study design details

Setting

The source populations are patients included in the Maccabi HCO database in Israel and the REPAR database in the Czech Republic.

Comparators

daily somatropin

Outcomes

Outcomes: The outcomes for the primary objective are Height, Height SDS, annual Height velocity, and annual Height velocity SDS. The secondary

objective outcomes of interest are weight, weight SDS, difference in weight SDS, Body mass index (BMI), BMI SDS, difference in BMI, difference in BMI SDS, bone age and difference in bone age, injection site reactions, treatment adherence and compliance, proportion of patients that switched back and reason for switch back to daily GH.

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

Maccabi HCO database in Israel

REPAR (REgistry of PAtients treated with gRowth hormone) database in the Czech Republic

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Data sources (types)

Electronic healthcare records (EHR)

Laboratory tests and analyses

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

Unknown