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: 30/04/2026

Study protocol

C0311030_SWITCH NIS Protocol_11Dec2025 Clean_Redacted.pdf (391.9 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:

Other

Study topic, other:

Paediatric growth disorders/Growth Hormone Deficiency treatment in children

Study type:

Non-interventional study

Scope of the study:

Evaluation of patient-reported outcomes

Data collection methods:

Secondary use of data

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

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.

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