

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

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Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000829

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### Study ID

1000000829

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### DARWIN EU® study

No

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### Study countries

 Czechia

 Israel

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### Study status

Ongoing

## Contact details

### Study institution contact

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Study contact

[noya.machtiger-azoulay@pfizer.com](mailto:noya.machtiger-azoulay@pfizer.com)

### 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

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### Study start date

Planned: 27/02/2026

Actual: 17/02/2026

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### 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

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**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

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**Study topic, other:**

Paediatric growth disorders/Growth Hormone Deficiency treatment in children

**Study type:**

Non-interventional study

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**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

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**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 somatrogen, 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 somatrogen.

Secondary Objectives:

- To evaluate and compare the safety profile of weekly somatrogen and daily somatropin in children with GHD
- To assess the proportion of patients that switched back to daily somatropin among patients receiving somatrogen

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- To assess reasons for switch-back among patients who switched back from somatrogen to daily GH
- To evaluate and compare adherence to growth hormone treatment of participants before and after switching to somatrogen treatment.

## Study Design

## Non-interventional study design

Cohort

## Study drug and medical condition

### Medicinal product name

GENOTROPIN

NGENLA

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

SOMATROGON

SOMATROPIN

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### Anatomical Therapeutic Chemical (ATC) code

(H01AC08) somatrogon

somatrogon

(H01AC01) somatropin

somatropin

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### 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.

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## **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)
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## **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.

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## **Comparators**

daily somatropin

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## **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

Unknown