# Intima Media Thickness in children with growth hormone treatment

**First published:** 10/04/2013

**Last updated:** 29/03/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS3800

**Study ID**

16717

**DARWIN EU® study**

No

**Study countries**

Germany

**Study description**

Comparing Intima media thickness (IMT) of children with and without growth hormone treatment (GH) Correlation of IMT to doses of GH, duration of GH treatment, blood pressure, lipids and glucoseComparing IMT in the time period

of 1 y under GH treatment

**Study status**

Finalised

# Research institutions and networks

## Institutions

### Vestische Kinderklinik Datteln

# Contact details

**Study institution contact**

Thomas Reinehr T.Reinehr@kinderklinik-datteln.de

**Study contact**

T.Reinehr@kinderklinik-datteln.de

**Primary lead investigator**

Thomas Reinehr

**Primary lead investigator**

# Study timelines

**Date when funding contract was signed**

Planned: 04/02/2013

Actual: 04/02/2013

**Study start date**
Planned: 15/04/2013

Actual: 15/04/2013

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**Data analysis start date**
Planned: 21/04/2014

Actual: 21/04/2014

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**Date of interim report, if expected**
Planned: 30/06/2014

Actual: 30/06/2014

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**Date of final study report**
Planned: 24/11/2014

Actual: 20/10/2014

## Sources of funding

- Other
- Pharmaceutical company and other private sector

## More details on funding

Ipsen, Vestische Kinderklinik Datteln

## Study protocol

Prüfplan.pdf (16.64 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

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

**Main study objective:**

to study the relationship between IMT and gorwth hormone treatment

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

Genotropin, Nutropin, Norditropin

**Medical condition to be studied**

Growth hormone deficiency

## Population studied

**Short description of the study population**

Children and adolescents with growth hormone deficiency.

**Age groups**

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)

**Special population of interest**

Other

**Special population of interest, other**

Growth hormone deficient patients

**Estimated number of subjects**

200

## Study design details

**Data analysis plan**

measures of risk

## Documents

**Study results**

IMT growth hormone.pdf (349.37 KB)

**Study publications**

Knop C, Wolters B, Lass N, Wunsch R, Reinehr T. Carotid intima-media thickness ...

# 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**

Unknown