

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

Data analysis start date

Planned: 21/04/2014

Actual: 21/04/2014

Date of interim report, if expected

Planned: 30/06/2014

Actual: 30/06/2014

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 growth 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