

A study on the tissue responsiveness to short term exogenous growth hormone in children with idiopathic short stature in relation to their response to long-term treatment

Submission date 19/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 12/01/2021	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

NL342, NTR380

Study information

Scientific Title

A study on the tissue responsiveness to short term exogenous growth hormone in children with idiopathic short stature in relation to their response to long-term treatment

Acronym

Dose-response study

Study objectives

The change in biochemical parameters of bone and collagen metabolism during a short term Growth Hormone (GH) dose-response study predicts the long-term effect of GH on growth. Idiopathic short stature is partially explainable by an abnormal tissue responsiveness to GH and Insulin-like Growth Factor 1 (IGF-1). The hypotheses of this study are:

1. GH therapy in a dosage of 6 IU/mw/day administered before puberty increases height velocity, height in adolescence and final height.
2. GH administration affects puberty onset and its duration.
3. GH administration affects quality of life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Idiopathic Short Stature (ISS)

Interventions

After randomisation, the control group did not receive treatment, and were followed yearly for growth and puberty assessment.

The treatment group underwent two three month periods of GH administration (1.5 IU/m²/day, 3.0 IU/m²/day) with three month washout periods in between. Thereafter 6 IU/m²/day was given until the beginning of puberty.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Growth Hormone (GH) and Insulin-like Growth Factor 1 (IGF-1).

Primary outcome(s)

Height at stop of therapy (at onset of puberty) and final height.

Key secondary outcome(s)

1. Timing of onset of puberty
2. Duration of puberty
3. Relation between long-term growth response (dependent variable) and short-term growth response on various dosages and in vitro responsiveness of cultured skin fibroblasts to GH and IGF-1
4. Effect of GH therapy on quality of life

Completion date

01/01/2009

Eligibility**Key inclusion criteria**

1. Height Standard Deviation Score (SDS) less than -2
2. Prepubertal
3. Aged between four to eight in females, or four to ten in males
4. GH response to provocation tests more than 20 mU/l
5. Normal sitting height:height ratio
6. Normal screening blood tests and urinalysis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 years

Upper age limit

10 years

Sex

All

Total final enrolment

40

Key exclusion criteria

Any systemic disease during childhood that limits the growth potential or may interfere with the evaluation of the effectiveness of therapy.

Date of first enrolment

01/01/1994

Date of final enrolment

01/01/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Center

Amsterdam

Netherlands

2300 RC

Sponsor information

Organisation

Pfizer B.V. (The Netherlands) (Pfizer Inc, New York, USA)

ROR

<https://ror.org/02bzf1224>

Funder(s)

Funder type

Research organisation

Funder Name

Netherlands Organization for Scientific Research (NWO)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2010	12/01/2021	Yes	No