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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

Registration date
19/12/2005

Overall study status
Completed

Last Edited
12/01/2021

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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/m^2 /day, 3.0 IU/m^2/day) with three month washout periods in between. Thereafter 6 IU/m^2/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 measure
Height at stop of therapy (at onset of puberty) and final height.

Secondary outcome measures
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

Overall study start date
01/01/1994

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 urinanalysis

Participant type(s)
Patient

Age group
Child

Lower age limit

4 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
40

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)

Sponsor details
P.O. Box 37
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Sponsor type
Not defined

ROR
https://ror.org/02bzf1224

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organization for Scientific Research (NWO)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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