ISRCTN82161629 https://doi.org/10.1186/ISRCTN82161629

A study on the efficacy of the combination of growth hormone (GH) and gonadotropin releasing hormone analogues (GnRHa) on adult height in children with idiopathic short stature

Submission date
19/12/2005

Recruitment status
No longer recruiting

Registration date
19/12/2005

Overall study status
Completed

Last Edited
24/08/2009

Condition category
Nutritional, Metabolic, Endocrine

[_] 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

Contact name
Prof J.M. Wit

Contact details
Leiden University Medical Center
Department of Pediatrics
P.O. Box 9600
Amsterdam
Netherlands
2300 RC
+31 (0)71 5262824
j.m.wit@lumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
GH+GnRHa study

Study objectives
A combined treatment of GH and GnRHa for 3 years in short adolescents with relatively early puberty leads to final height gain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Multicentre randomised open label active controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Small for Gestational Age (SGA), children with persistent short stature

Interventions
Daily injections of Growth Hormone (GH) and monthly injections with GnRHa (Decapeptyl) for 3 years.
Regular controls at the clinic, blood investigations for effect and safety parameters, yearly X-rays of the hand, and yearly psychological assessment.
At final height, growth, psychological assessment, bone mineral density.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Final height SDS minus initial height SDS

Secondary outcome measures
1. Final height SDS
2. Final height SDS minus initial height SDS
3. Final height SDS minus target height
4. Body mass index
5. Bone mineral density
6. Quality of life

Overall study start date
01/10/1993

Completion date
01/07/2006

Eligibility

Key inclusion criteria
40 adolescents in early puberty, with a height <-2 Standard Deviation Score (SDS) or with a height SDS between -1 and -2, but a predicted adult height SDS <-2

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
40

Key exclusion criteria
Disorders or medication influencing growth

Date of first enrolment
01/10/1993

Date of final enrolment
01/07/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Center
Amsterdam
Netherlands
2300 RC

Sponsor information

Organisation
Pfizer B.V. (Netherlands) (Pfizer Inc, New York)

Sponsor details
P.O. Box 37
Capelle a/d IJssel
Netherlands
2900 AA
+31 (0)10 4064200
sigrid.van.den.broek@pfizer.com

Sponsor type
Not defined

ROR
https://ror.org/02bzf1224

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Utrecht (UMCU) (Netherlands)

Funder Name
Netherlands Organisation for Scientific Research (NWO) (Netherlands)

Alternative Name(s)

Netherlands Organisation for Scientific Research, Dutch National Scientific Foundation, Dutch National Science Foundation, Dutch Research Council (Nederlandse Organisatie voor Wetenschappelijk Onderzoek), NWO:Nederlandse Organisatie voor Wetenschappelijk Onderzoek, Nederlandse Organisatie voor Wetenschappelijk Onderzoek (NWO), Dutch Research Council, Dutch Research Council, Netherlands, NWO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Netherlands

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	01/04/2007		Yes	No