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

Recruitment status No longer recruiting	Prospectively registered	
	☐ Protocol	
Overall study status	Statistical analysis plan	
Completed	[X] Results	
Condition category Nutritional Metabolic Endocrine	[] Individual participant data	
	No longer recruiting Overall study status Completed	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof J.M. Wit

Contact details

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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