

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	☐ Prospectively registered
Registration date 19/12/2005	Overall study status Completed	☐ Protocol
Last Edited 24/08/2009	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ Results
		☐ 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

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

Primary study design

Interventional

Study design

Multicentre randomised open label active controlled parallel group trial

Study type(s)

Treatment

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(s)

Final height SDS minus initial height SDS

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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)

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, The Dutch Research Council (NWO), Dutch Research Council, Netherlands, NWO

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2007		Yes	No