

Controlled growth hormone (GH) study in children with Prader-Willi syndrome

Submission date 28/04/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol ☐ Statistical analysis plan ☒ Results ☐ Individual participant data
Registration date 28/04/2006	Overall study status Completed	
Last Edited 05/11/2012	Condition category Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR628

Study information

Scientific Title
Multicentre, randomised, controlled growth hormone study in children with Prader-Willi syndrome: effects on growth, body composition, activity level and psychosocial development

Study objectives

Growth hormone (GH) treatment improves height, weight, body composition, muscle strength, activity level, psychosocial development, psychomotor development in infants, metabolism and respiratory function versus no GH treatment in children with Prader-Willi syndrome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local medical ethics committee gave approval

Primary study design

Interventional

Study design

Multicentre randomised active-controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Prader-Willi syndrome

Interventions

Treatment with GH: Genotropin® 1 mg/m²/day subcutaneously (sc) versus no GH-treatment. Dietary and exercise advice.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Genotropin®

Primary outcome(s)

To assess effects of GH-treatment versus no GH-treatment in children with Prader-Willi syndrome on:

1. Height, weight, body composition, muscle mass, muscle strength and daily life activity
2. Cognition, behaviour and social emotional development
3. Resting energy expenditure
4. Psychomotor development in infants

Key secondary outcome(s)

To study the effect of additional dietary advice and physical exercise on body composition in children with Prader-Willi syndrome treated with GH versus not treated with GH.

Completion date

01/05/2007

Eligibility

Key inclusion criteria

1. Genetically confirmed diagnosis of Prader-Willi syndrome
2. Age between 6 months and 16 years at start of the study
3. Bone age less than 16 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 Months

Upper age limit

16 Years

Sex

All

Key exclusion criteria

1. Extremely low dietary intake
2. Severe scoliosis (consult spinal surgeon)
3. Body mass index (BMI) SDS greater than +3
4. In children greater than 3 years, height SDS less than 0 unless weight for height greater than +2SDS

Date of first enrolment

23/04/2002

Date of final enrolment

01/05/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Dutch Growth Foundation

Rotterdam

Netherlands

3016 AH

Sponsor information

Organisation

Dutch Growth Foundation (Netherlands)

Funder(s)

Funder type

Industry

Funder Name

Pfizer (Netherlands)

Alternative Name(s)

Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen, Pfizer Inc

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

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 on effect of GH-treatment on incidence of scoliosis	01/04/2009		Yes	No
Results article	results on effect of GH-treatment on bone density	01/10/2009		Yes	No
Results	ovarian function results				

[article](#)

01/09/2012

Yes

No