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

Submission date	Recruitment status
28/04/2006	No longer recruiting
Registration date	**Overall study status**
28/04/2006	Completed
Last Edited	**Condition category**
05/11/2012	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

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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

Study design
Multicentre randomised active-controlled parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prader-Willi syndrome

Interventions
Treatment with GH: Genotropin® 1 mg/m^2/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 asses 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