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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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### 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 measure
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

### Secondary outcome measures
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.

### Overall study start date
23/04/2002

### 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

### Age group
Child

### Lower age limit
6 Months

### Upper age limit
16 Years

### Sex
Both

### Target number of participants
85

### 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)

**Sponsor details**
Westzeedijk 106
Rotterdam
Netherlands
3016 AH

**Sponsor type**
Charity

# 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

### Funding Body Type
Government organisation

### Funding Body Subtype
For-profit companies (industry)

### Location
United States of America

# 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 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 article | ovarian function results | 01/09/2012 | | Yes | No |