

Effects of growth hormone treatment after final height in Prader-Willi Syndrome

Submission date 05/09/2007	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 05/09/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/11/2016	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Dederieke Festen

Contact details
Dutch Growth Foundation
Westzeedijk 106
Rotterdam
Netherlands
3016 AH
+31 (0)10 225 1533
d.festen@erasmusmc.nl

Additional identifiers

Protocol serial number
NTR1038

Study information

Scientific Title
Effects of growth hormone treatment after final height in Prader-Willi Syndrome: a double-blind multicentre, cross-over study on the effects of growth hormone versus placebo on body composition and psychosocial behaviour in transition

Study objectives

Growth Hormone (GH) treatment after reaching final height is beneficial for body composition and social wellbeing in young adults with Prader-Willi Syndrome (PWS).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Multicentre randomised double-blinded placebo-controlled crossover group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Prader Willi Syndrome

Interventions

Treatment with GH: Genotropin 0.67 mg/m²/day subcutaneous (s.c.) or placebo.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Growth Hormone (Genotropin®)

Primary outcome(s)

1. Body composition
2. Carbohydrate metabolism
3. Psychosocial functioning
4. Sleep-related breathing disorders
5. Circulating lipids
6. Blood pressure

Key secondary outcome(s)

1. Thyroid hormone levels, Insulin-like Growth Factor (IGF-I) and IGF binding proteins, adiponectin, ghrelin
2. Compliance to the diet

Completion date

01/10/2011

Eligibility

Key inclusion criteria

1. Young adults, originally participating in the Dutch GH study in PWS children (ISRCTN49726762) or otherwise GH-treated patients
2. Final height is reached or epiphysial fusion is complete
3. Treated with GH during childhood for at least two years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Non-cooperative behaviour
2. Extremely low dietary intake of less than minimal required intake according to World Health Organisation (WHO)
3. Medication to reduce weight (fat)

Date of first enrolment

01/10/2007

Date of final enrolment

01/10/2011

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	16/11/2016		Yes	No