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

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Multicentre randomised double-blinded placebo-controlled crossover group trial

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Prader Willi Syndrome

Interventions

Treatment with GH: Genotropin 0.67 mg/m^2/day subcutaneous (s.c.) or placebo.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Growth Hormone (Genotropin®)

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

01/10/2007

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

Age group

Adult

Sex

Both

Target number of participants

20

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

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

Research organisation

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	16/11/2016		Yes	No