ISRCTN24648386 https://doi.org/10.1186/ISRCTN24648386

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
Registration date	**Overall study status**	[_] Statistical analysis plan
05/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/11/2016	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
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

Study type(s)
Treatment

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(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