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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28633

Source
Nationaal Trial Register

Brief title
n/a

Health condition

Prader-Willi Syndrome
Prader-Willi Syndroom

Sponsors and support

Primary sponsor: Dutch Growth Foundation
Source(s) of monetary or material Support: Pfizer

Intervention

Outcome measures

Primary outcome

To assess effects of GH-treatment versus placebo on
a. body composition

b. carbohydrate metabolism
c. psychosocial functioning
d. sleep-related breathing disorders
e. circulating lipids
f. blood pressure

Secondary outcome

1. To study the effects of GH-treatment versus placebo on thyroid hormone levels, IGF-I and IGF binding proteins, adiponectin, ghrelin.
2. To study compliance to the diet.

Study description

Background summary

Background: GH improves height velocity, and body composition in PWS children. Preliminary data also suggest improvement of psychosocial functioning during GH. When epiphysial fusion is complete and final height is reached, GH-treatment has to be discontinued. However, discontinuation of GH results in a decrease of lean body mass, an increase of body fat percentage and a deterioration of psychosocial behaviour. A preliminary study showed that also young adults with PWS might benefit from GH-treatment, with regard to body composition, and psychosocial wellbeing.
Objectives:
Primary objectives
To assess effects of GH-treatment versus placebo on
- body composition
- carbohydrate metabolism
- psychosocial functioning
- sleep-related breathing disorders
- circulating lipids
- blood pressure
Secondary objectives
- To study the effects of GH-treatment versus placebo on thyroid hormone levels, IGF-I and IGF binding proteins, adiponectin, ghrelin.
- To study compliance to the diet.
Patients: subjects with PWS, aged 18-24 years, who reached final height after they were treated with GH according to the Dutch National GH study in children with PWS (ISRCTN49726762), or after they were otherwise treated with GH (at least 2 years) during childhood.
Intervention: Treatment with GH: Genotropin 0.67 mg/m2/day s.c. or placebo
Design/Assessments: After stratification for BMI, gender, originally followed in the GH study vs. otherwise GH-treated patients, subjects will be randomized to either placebo or GH-treatment group, according to a double blind, placebo-controlled cross-over design during the

first 2 years. After 2 years, all patients receive GH treatment in a dose of 0.67 mg/m2/day, after ATT-GHRH test has been performed. Anthropometric assessments and blood pressure will be performed every 3 months. Six-monthly, assessment of body composition (DXA), carbohydrate metabolism and circulating lipids and other laboratory parameters will be performed. Yearly, evaluation of sleep-related breathing (polysomnography), and cognition and behaviour (GIT, TVZ) will be performed.

Study objective

GH treatment after reaching final height is beneficial for body composition and social wellbeing in young adults with PWS

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

1. Young adults, originally participating in the Dutch GH study in PWS children (ISRCTN49726762) or otherwise GH-treated patients and

2. Final height is reached or epiphysial fusion is complete and
3. Treated with GH during childhood for at least 2 years

Exclusion criteria

1. non cooperative behaviour
2. extremely low dietary intake of less than minimal required intake according to WHO
3. medication to reduce weight (fat)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2007
Enrollment:	20
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1009
NTR-old	NTR1038
Other	: n/a
ISRCTN	ISRCTN24648386

Study results

Summary results
n/a