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

Gepubliceerd: 16-08-2007 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28633

Bron
Nationaal Trial Register

Verkorte titel
n/a

Aandoening

Prader-Willi Syndrome
Prader-Willi Syndroom

Ondersteuning

Primaire sponsor: Dutch Growth Foundation
Overige ondersteuning: Pfizer

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2007
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
n/a