Controlled growth hormone study in children with Prader Willi Syndrome.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26880

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Prader Willi Syndrome

Sponsors and support

Primary sponsor: The study is financially supported by Pfizer
Source(s) of monetary or material Support: Dutch Growth Foundation

Intervention

Outcome measures

Primary outcome

To asses effects of GH-treatment vs. no GH-treatment in children with PWS on:

height, weight, body composition,
muscle mass, muscle strength and daily life activity.
Cognition, behaviour and social emotional development. Resting Energy Expenditure.

Psychomotor development in infants.

Secondary outcome

To study the effect of additional dietary advise and physical exercise on body composition in children with PWS treated with GH vs, not treated with GH.

Study description

Background summary

Summary of the Dutch National Growth Hormone Study in Children with Prader Willi Syndrome.

Title:

Multicenter, randomized, controlled growth hormone study in children with Prader Willi Syndrome: effects on growth, body composition, activity level and psychosocial development" MEC 2001/230.

Short title:

Controlled growth hormone study in children with Prader Willi Syndrome.

Background:

Children with Prader Willi Syndrome have often short stature and have an abnormal body composition (Increased fatpercentage and decreased lean body mass). Physical activity level is therefore decreased in children with Prader Willi Syndrome. Children with Prader Willi syndrome often have mental retardation and behavioral problems.

Recent studies showed an improvement in height and body composition during growth hormone (GH) treatment in children with Prader Willi Syndrome. Preliminary data showed also an improvement in activity level, metabolism, respiratory function, behaviour and social-emotional development.

Aim:

To study the effects of GH-treatment versus no GH treatment in children with Prader Willi

Syndrome on changes in height, weight, body composition, muscle strength, activity level, psychosocial development, metabolism and respiratory function.

Patients:

85 children with PWS, aged 6 mo. to 16 years at start of the study.

Intervention:

Treatment with GH: Genotropin ® 1mg/m2/d s.c.

Design:

Children will be randomly divided into 3 subgroups: infants, prepubertal children and adolescents. Infants and prepubertal children will be treated in a controlled design. (Start GH-treatment at start of the study or after 1 or two years resp.) Adolescents will be treated in a non-controlled design. All children over the age of 3 will receive dietary advice and an exercise program.

Anthropometric assessments will be performed every 3 months.

Yearly assessment of body composition (DEXA), metabolism (Indirect calorimetry), muscle strength (quadriceps dynamometry) and activity level (Activity monitoring) will be performed.

Cognition (subtests of WISC, WPPSI or BOS), behaviour (DBC), social emotional development (VABS) and quality of life (DUX 25) will be measured yearly.

In a subgroup of children pulmonary CO2 responsiveness will be measured.

Objectives:

Primary:

To asses effects of GH-treatment vs. no GH-treatment in children with PWS on
Height, weight, body composition
Muscle mass, muscle strength and daily life activity
Cognition, behaviour and social emotional development
Resting Energy Expenditure
CO2 responsiveness.

Secondary:

To study the effect of additional dietary advise and physical exercise on body composition in

children with PWS treated with GH vs, not treated with GH.

Study objective

GH treatment improves height, weight, body composition, muscle strength, activity level, psychosocial development, psychomotor development in infants, metabolism and respiratory function versus no GH treatment in children with Prader Willi Syndrome.

Study design

N/A

Intervention

Treatment with GH: Genotropin ® 1mg/m2/d s.c. vs. no GH-treatment.

Dietary and exercise advice.

Contacts

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Eligibility criteria

Inclusion criteria

1. Genetically confirmed diagnosis of Prader Willi Syndrome;

2. Age between 6 months and 16 years at start of the study;

3. Bone age less than 16 years.

Exclusion criteria

1. Extremely low dietary intake;

2. Severe scoliosis (consult spinal surgeon);

3. BMI SDS > +3SDS;

4. In children > 3 years, height SDS < 0 unless weight for height> +2SDS.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-04-2002
Enrollment:	85
Type:	Actual

Ethics review

Positive opinion

Date:	15-03-2006
Application type:	First submission

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	NL572
NTR-old	NTR628
Other	: N/A
ISRCTN	ISRCTN49726762

Study results

Summary results
N/A