Predictive diagnostic study on the short-term metabolic effects of recombinant human Growth Hormone treatment in growth hormone deficiency and small for gestational age children.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Observational non invasive

Summary

ID

NL-OMON36604

Source
ToetsingOnline

Brief title
Metabolic effects of growth hormone.

Condition

- Hypothalamus and pituitary gland disorders

Synonym
growth hormone deficiency / insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Novo Nordisk

Intervention

Keyword: Growth Hormone, Growth hormone deficiency, Metabolic effects, Small for gestational age

Outcome measures

Primary outcome

The relation between short time effects of rhGH treatment on total body water

(TBW) and total energy expenditure (TEE) in growth hormone deficient and small

for gestational age children and the long-term change in height SDS after one

year.

Secondary outcome

What effect has GH on a number of metabolic risk parameters that are typical

parameters for the metabolic syndrome in adults?

Study description

Background summary

Short stature is a frequently seen problem for the paediatric endocrinologist.
As the most common endocrine cause the diagnosis growth hormone deficiency (GHD) is stated. To diagnose GHD is troublesome, because of the paucity of biological endpoints. Momentarily, GHD is confirmed in children by means of growth hormone provocation tests, but the outcome of these endocrine tests is not discriminative and does not adequately predict the effect of therapy on growth. Besides its growth-promoting effect, growth hormone (GH) also influences metabolism. The changes in metabolism might be useful as a predictor of the growth effect.
There seems to be an association between the disturbance of the growth hormone axis and several features of the metabolic syndrome (MS). The MS is characterized as a cluster of metabolic abnormalities that strongly increase

the risk of cardiovascular disease and type II diabetes mellitus in adulthood. It is known that both GH and insulin-like growth factor-I (IGF-I) reduces these cardiovascular risk factors and has beneficial effects on body composition by reducing fat mass and increasing muscle mass (1). Beside the GHD children also children born small for gestational age (SGA) seem to benefit from rhGH treatment.

Study objective

The primary objective of this study is to assess the relation between the short term metabolic changes after start of rhGH therapy and the long term change in height SDS after one year of treatment. Secondly, we want to assess the effects of GH on metabolic risk parameters which are typical parameters for the metabolic syndrome in adults.

Study design

The study design is a predictive diagnostic study monitoring the metabolic effects and efficacy of rhGH in GHD and SGA subjects. Total body water (TBW), total energy expenditure (TEE), basal metabolic rate (BMR) and physical activity level (PAL) measurements are performed over a 2-wk period using the doubly labeled water (DLW) method before and during GH treatment. Markers of metabolic risk factors will be determined during routine blood controls. Baseline characteristics of growth patterns, blood pressure, BMI and waist circumference are collected every three months during routine controls. Furthermore, the measurements will be linked with the anthropometric parameters of each individual assembling a prognostic growth profile, therefore the children will be followed during one year of treatment to evaluate the change in height standard deviation score (SDS).

Intervention

All subjects receive recombinant human (rh)GH in accordance with international guidelines.

Study burden and risks

Before the start of the study, subjects will be screened for underlying growth pathology accordingly the Dutch Growth Research Foundation guidelines , including growth hormone test. When enrolled in the study, rhGH treatment will be started. All visits are linked with the routine visit controls accordingly to the guidelines, except the visit before start GH treatment and the six week visit. Throughout these visits, routine blood controls are used for determining metabolic risk markers, no extra blood controls are used. The total amount of extra drawn blood would be maximum 10 ml. The risks of rhGH treatment are given in the prescribing information, further are those of the doubly labeled water

(DLW) and Ventilated Hood (VH) method, which are none.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All children scheduled for growth hormone treatment, fulfilling the next criteria: ;#Children born small for gestational age (SGA) without catch up growth:
- Children born with a birth length and/or weight < -2 SDS for gestational age
- Short stature defined as height SDS below -2.5 according to the Dutch National Growth
;#Children with growth hormone deficiency (GHD):
- GHD is confirmed in all patients who during an arginine and clonidine provocation test show a peak GH level of < 20 mU/l. ;#Age equal to or above four years.

Exclusion criteria

- Children with a chronological or bone age greater than 8 years for girls and 10 years for boys, because of the influence of puberty
- Children with syndromes or diseases that influence growth otherwise than GDH or SGA.
- Expected non-compliance

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2011
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-12-2011
Application type:	First submission
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24096
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
ClinicalTrials.gov	NCT2895
CCMO	NL34670.068.10
OMON	NL-OMON24096