Metabole effecten van groeihormoon.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24096

Source
NTR

Brief title
Metabolic effects of growth hormone.

Health condition

Growth Hormone
Growth hormone deficiency
Diagnostic problems of growth hormone tests

Sponsors and support

Primary sponsor: Maastricht University Medical Centre (MUMC)
PO box 5800
6202 AZ Maastricht
The Netherlands
Telephone +31 43 387 5239

Source(s) of monetary or material Support: Novo Nordisk

Intervention

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. Beside the GHD children also children born small for gestational age (SGA) seem to benefit from rhGH treatment.
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).

Study objective

The hypothesis is that rhGH treatment in children with GHD or SGA results within 6 weeks in a change of metabolism recognizable as an increase of total energy expenditure (TEE). These change in metabolism can be used as a predictor of growth response in the first year of

treatment.

Study design

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 6 weeks of 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

N/A

Contacts

Public
Department of paediatrics
Maastricht University Medical Centre (MUMC)
PO box 5800
D.A. Schott
Maastricht 6202 AZ
The Netherlands
+31 (0)43 3875239
Scientific
Department of paediatrics
Maastricht University Medical Centre (MUMC)
PO box 5800
D.A. Schott
Maastricht 6202 AZ
The Netherlands
+31 (0)43 3875239

Eligibility criteria

Inclusion criteria

1. All children scheduled for growth hormone treatment, fulfilling the next criteria:

A. Children born small for gestational age without catch up growth;

B. Children born with a birth length and/or weight < -2 SDS for gestational age (Niklasson);

C. Short stature defined as height SDS below -2.5 according to the Dutch National Growth References of 1997 and height of ≥ 1.3 SDS below target height SDS.

2. Children with growth hormone deficiency:

A. GHD is confirmed in all patients who during an arginine and clonidine provocation test show a peak GH level of < 20 mU/l.

3. Informed consent;

4. Age ≥ four years.

Exclusion criteria

1. Children with a chronological or bone age greater than 8 years for girls and 10 years for boys, because of the influence of puberty;

2. Children younger that 4 years of age;

3. Children with syndromes or diseases that influence growth otherwise than GDH or SGA;

4. Expected non-compliance based on earlier knowledge over the patient by the opinion of the endocrinologist.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control: N/A , unknown

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-07-2011
Enrollment: 30
Type: Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 36604
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2756
NTR-old	NTR2895
CCMO	NL34670.068.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36604

Study results

Summary results
N/A