Metabole effecten van groeihormoon.

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24096

Bron
Nationaal Trial Register

Verkorte titel
Metabolic effects of growth hormone.

Aandoening

Growth Hormone
Growth hormone deficiency
Diagnostic problems of growth hormone tests

Ondersteuning

Primaire sponsor: Maastricht University Medical Centre (MUMC)
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Overige ondersteuning: Novo Nordisk

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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).

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel

Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2011
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36604
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A