# Evaluation of withdrawing growth hormone treatment in mid-puberty in stead of at final height in a group of growth hormone deficient adolescents

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON26765

**Bron**
Nationaal Trial Register

**Verkorte titel**
GROEISPURT

**Aandoening**

growth hormone deficiency

growth hormone treatment

cost-efficiency

### Ondersteuning

**Primaire sponsor:** VU medisch centrum
**Overige ondersteuning:** ZonMw<br>
Zorgverzekeraars Nederland

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Adult height (AH) minus target height (TH) SDS.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale: If children who are diagnosed as idiopathic isolated growth hormone deficiency are retested for growth secretion after adult height has been reached, a normal test result is often observed. It appears plausible that if a normal GH secretion is observed in mid-puberty, GH treatment may only have a minor effect on adult height. We hypothesize that withdrawing GH treatment in mid-puberty has no negative effect on attained adult height and on patients' satisfaction with adult height.

Objective: The aim of this study is to assess whether withdrawing GH treatment after mid-puberty in adolescents with idiopathic isolated GH deficiency, who showed a normal result in a GH stimulation test at retesting, is as effective as continuing GH until adult height.

Study design: prospective patient preference design with additional historic control group, studied up to adult height. All children with IIGHD will be retested in mid-puberty, according to the current treatment protocol.
If GH secretion is normal, patients will be asked if they prefer to continue GH treatment until near-adult height is reached (traditional approach) or discontinue GH treatment. We expect that the preference of each choice will be approximately 50%. It is expected that groups will differ in baseline characteristics (e.g. those who choose discontinuing GH may be older and taller). Because the number of included patients will be too low (and the between-group differences too large) to show statistically significant “non-inferiority” of discontinuing GH at mid-puberty, a retrospective analysis will be performed of growth, pubertal stages and bone age of a historic control group (anonimized) with IIGHD, in whom a normal GH provocation test was found after stopping GH treatment at final height. Based on these data, a model will be constructed of expected height gain on GH treatment as a function of sex, age, bone age, Tanner stage, GH peak in childhood, GH peak at retesting, and GH dosage. For both prospectively followed groups the expected height gain at inclusion will be calculated based on the model. At the end of the observation period, the effectively attained height gain in both groups will be compared with the predicted one. We hypothesize that the difference in attained minus predicted height gain in both groups will not be significantly different from zero, and that the 95% CI will exclude a difference >0.5 SD to the detriment of the group who discontinued GH in mid-puberty.

Study population: GH treated adolescents with partial IIGHD (GH peak at diagnosis >5 mU/L and <30 mU/L) who reached mid-puberty (boys: Tanner stage G3 or G4, testicular volume >12 ml and bone age 13-16 years; girls: Tanner stage B3 or B4 and bone age 11-14

years). Potential participants are identified in the national database of the Stichting Kind en Groei (SKG). Patients with a GH peak of >20 mU/L at retesting are eligible for inclusion.

Intervention (if applicable): Withdrawing GH treatment in mid-puberty versus continuing GH treatment until near adult height (growth velocity <2 cm/yr)

**Doel van het onderzoek**

Assuming that 80 % of the adolescents have a normal growth hormone secretion when retesting in puberty, we think there is no significant difference in final height between the group that discontinue growth hormone treatment (after a normal test in mid puberty) and the group that continues growth hormone treatment.

**Onderzoeksopzet**

Follow up of patients who continue growth hormone treatment is according to standard care (every 3-4 months). Patients who choose to discontinue growth hormone treatment are followed yearly.

**Onderzoeksproduct en/of interventie**

Withdrawing GH treatment in mid-puberty versus continuing GH treatment until near adult height (growth velocity <2 cm/yr)

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

idopathic isolated growth hormone deficiency

GH peak at diagnosis > 5 mU/L and < 30 mU/L

Mid puberty (boys: Tanner G3 or G4, testicular volume > 12 ml and bone age 13-16 years; girls: Tanner B3 or B4, bone age 11-14 years)

GH peak at retesting mid puberty > 20 mU/L

Treated with GH for at least 3 years

Informed consent

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Medical condition or medication influencing growth

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Niet-gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Actieve controle groep |

## Deelname

Nederland
Status: Werving gestart

| | |
|---|---|
| (Verwachte) startdatum: | 01-09-2016 |
| Aantal proefpersonen: | 120 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 15-08-2017 |
| Soort: | Eerste indiening |

# 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 | NL6440 |
| NTR-old | NTR6618 |
| Ander register | METc VUmc : 2016.396 |

# Resultaten