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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26765

Source
Nationaal Trial Register

Brief title
GROEISPURT

Health condition

growth hormone deficiency

growth hormone treatment

cost-efficiency

Sponsors and support

Primary sponsor: VU medisch centrum
Source(s) of monetary or material Support: ZonMw
Zorgverzekeraars Nederland

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Adult height SDS, total pubertal growth (cm), and satisfaction with attained adult height.

Study description

Background summary

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)

Study objective

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.

Study design

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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

Medical condition or medication influencing growth

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2016
Enrollment:	120

Type:	Anticipated

Ethics review

Positive opinion Date:	15-08-2017
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	NL6440
NTR-old	NTR6618
Other	METc VUmc : 2016.396

Study results