Effect of Growth Hormone replacement therapy on cardiovascular risk factors in adult patients with severe growth hormone deficiency: association with IGF-I concentration

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Next to cardiovascular risk factors (main objectives: body composition and lipid profile; secondary objectives: remainder) we investigate the effect of GH treatment on glucose metabolism, physical performance, and neuropsychological functioning of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Interventional

Summary

ID

NL-OMON39563

Source
ToetsingOnline

Brief title
GH and cardiovascular risk factors

Condition

- Hypothalamus and pituitary gland disorders

Synonym
growth hormone deficiency

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMW;Divisie I Beheer B.V. VUmc

Intervention

Keyword: Cardiovascular risk factors, Growth hormone deficiency, Growth Hormone replacement therapy

Outcome measures

Primary outcome

The difference in cardiovascular risk factors at baseline and after 24 weeks of

GH treatment with different target levels of IGF-I concentration.

Secondary outcome

Secundary we investigate the effect of GH treatment on glucose metabolism,

physical performance, and neuropsychological functioning at different levels of

IGF-I.

Study description

Background summary

Abnormally low and high levels of insulin-like growth factor-I (IGF-I) are both associated with increased metabolic risk. Since (U-shaped) associations of IGF-I, within the normal range, have also been found with cardiovascular risk factors and disease in the general population, it would be interesting to investigate if this association can also be found in growth hormone deficient (GHD) adults treated with Growth Hormone (GH).

Study objective

Next to cardiovascular risk factors (main objectives: body composition and lipid profile; secondary objectives: remainder) we investigate the effect of GH treatment on glucose metabolism, physical performance, and neuropsychological functioning of different levels of IGF-I in GH treated GHD men and women.

Study design

Open-label randomized trial

Intervention

At entry subjects are already receiving GH treatment according to general clinical practice, and are expected to demonstrate an IGF-I concentration of 0 * 1 SD score (SDS) (ND). The group of men and group of women will be randomized to receive either a decrease of their regular dose of GH treatment (IGF-I target level of -2 * -1 SDS) (LD), or an increase of their regular dose, (IGF-I target level of 1 * 2 SDS) (HD) for at least 24 weeks.

Study burden and risks

Subjects have to visit the research facility two times, each 24 weeks apart. Most of the investigational techniques used in the protocol are employed routinely in the clinic. No invasive investigation will be conducted, accept blood sampling, which will be realized by a skilled investigator. Because GH treatment is already used by each participant for at least one year, and dosed within the reference range, serious adverse events are not to be expected, but will be monitored closely. Eventually, outcome of the study could help to prevent over- or undertreatment of GHD adults with regard to the outcome measures included in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Ongoing surveillance at our centre (VUmc, Amsterdam)
- GH treated (at least one year)
- Men and women with an age between 20 and 65 years, both childhood as adult onset GHD
- Stable substitution therapies for other pituitary hormone deficiencies

Exclusion criteria

- Subjects with a craniopharyngioma as cause of their GHD or pituitary deficiencies
- Contraindications for the use of Growth Hormone treatment
- (Receiving treatment for) malignant disease (in the past)
- Cardiovascular event less than one year prior to inclusion
- Participation in other studies
- Subjects, who in the opinion of the investigator, are unsuitable in any other way to participate in this study

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-05-2013
Enrollment:	32
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Genotropin
Generic name:	somatropine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Humatrope
Generic name:	somatropine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Norditropin
Generic name:	somatropine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Zomacton
Generic name:	somatropine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-01-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-05-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2012-005066-36-NL
CCMO	NL42315.029.12