GH receptor polymorfism: the effects on growth hormone substitution in patients with growth hormone deficiency

Published: 26-01-2007
Last updated: 09-05-2024

Aim of the study is to study the influence of GH receptor polymorfisms on the effects of growth hormone substitution in aduts with GH deficiency.

Ethical review	Approved WMO
Status	Pending
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON30312

Source
ToetsingOnline

Brief title
GH receptor polymorfisms in adult GHD

Condition

- Hypothalamus and pituitary gland disorders

Synonym
growth hormone deficiency

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: adults, effects of GH substitution, GH deficiency, GH receptor polymorfism

Outcome measures

Primary outcome

1. The prevalence of the GH receptor polymorfisms.

2. The interactions of efficacy of GH substitution with GH receptor

polymorfisms.

Secondary outcome

Not applicable.

Study description

Background summary

Growth hormone (GH) substitution in adults with GH deficiency has beneficial effects on bone mineral density, body composition, cardiovascular parameters, and quality of life. Recently, a polymorfism in the GH receptor (d3-GHR, a genomic deletion of exon 3) has been described, which affects the growth velocity after start of growth hormone substitution. Patients with this polymorfism have a higher growth velocity. The binding of GH to the receptor is unchanged in the polymorfism, but signal transduction seems to be enhanced. The allel-prevalence of this polymorfism is 25 to 32% with an hymozygous frequency of 9 to 14%.

Study objective

Aim of the study is to study the influence of GH receptor polymorfisms on the effects of growth hormone substitution in aduts with GH deficiency.

Study design

This is a cross-sectional study.

Study burden and risks

Patients will be invided to participate in 1 visit of approximately 30 minutes.
Blood will be drawn at that occassion.

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

- Informed consent
- All patients with growth hormone deficiency who have been treated with growth hormone substitution for at least one year

Exclusion criteria

- Known pathogenic mutations in the growth hormone receptor that caused growth hormone deficiency.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2006
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL14536.058.06