Diagnose of GH-deficiency: comparing the reliability of a dietary-protein test with conventional Growth Hormone Stimuation Tests

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Comparing the reliability of a dietary-protein test with conventional Growth Hormone Stimulation Tests.

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31236

Source
ToetsingOnline

Brief title
Diagnose of Gh-deficiency

Condition

- Other condition
- Hypothalamus and pituitary gland disorders

Synonym
growth retardatrion, short-stature

Health condition

groeistoornissen

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Center for Food Sciences
Source(s) of monetary or material Support: TIFN

Intervention

Keyword: GH-deficiency, Growth hormone Stimuation Test, protein-test

Outcome measures

Primary outcome

A difference in reliability in the diagnose of GH-deficiency with the GHST*s

and the protein test, using TBW-test.

TBW-test is the evaluation test in this study to compare the predicting power

of the diagnostic tests. TBW-test is used to evaluate GH-therapy after 6 weeks.

Secondary outcome

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Study description

Background summary

Current GHST*s to predict GH-deficiency in children are seriously criticized, because the costs, side-effects and the low reliability of the results to predict GH-deficiency. So there is a need for a more potent and physiological GHST.

Study objective

Comparing the reliability of a dietary-protein test with conventional Growth Hormone Stimulation Tests.

Study design

The experiment will be carried out by the pediatrist in the academic hospital

of Maastricht, immediately after standard tests for diagnosis of GH deficiency. This test include the measurement of GH responses to intravenous administration of arginine. After the standard tests, an extra test will be carried out. In this test subjects receive a protein drink, containing complete soy protein. Soy protein is a dietary protein, containing relatively high levels of arginine and has been shown in our preceding studies to stimulate GH release in adult women more potent in comparison with a solution of arginine.
Test persons receive a drink after the first sample and GH will be measured every 20 min for 5 h.

Intervention

All children undergo an arginine-growth hormone stimulation test and one other test (L-dopa, sleeping or chondiline), because of suspected growth retardation based on one of the anthropametric criteria (inclusion criteria). In this experiment, one test is added, the protein-test. The product soyprotein, use in this test, is produced by NIZO (Nederlands Instituut Zuivel Onderzoek) and is a solution of food-grade soyprotein.

Study burden and risks

This study is a non-therapeutic groups related study, with children from 6-12 years old. This study could not conducted without the participation of subjects belonging to this group, because GH-deficiency is always determine in this age-group and to make a comparison between the current diagnostic test and an additional one, the same patients are needed. In healthy adults, we showed a bigger increase in GH-release after oral ingestion of soyprotein in comparison with arginine. In this study, we*d like to compare both tests, with respect to determining of GH-deficiency in children.
The study does not include any risks for the subjects, apart from the usual risks of blood sampling as bruises and little swellings. There are absolutely no other risks, because the same catheter is used in all experiments. The same catheter that is implemented for blood sampling in these experiments , so no extra catheter will be implemented.
There are no risks for the subjects in using the protein drink, as the protein used are food-proof and present in our daily diet.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Eligibility for GHST's is based on one or more of the anthropometric criteria characterizing GH deficient patients:
* Height less than -2,5 SDS
* Deviation from target height more than 1.3 SDS
* Deviation of growth more than -0.25 SDS.

Exclusion criteria

Children will be excluded if other reasons than those related to GH for growth retardation were present. Because it is known that girls with Turner syndrome show a growth response to GH therapy, they will be included in the tests.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Not approved

Date:	03-07-2007
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL17353.000.07