Effects of protiens on GH secretory patterns in obese and non-obese elderly

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To investigate if the GH-promoting effect of gelatine- protein is present in non-overweight and overweight elderly people.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32139

Source
ToetsingOnline

Brief title
Effects of proteins on GH secretion in elderly

Condition

- Other condition

Synonym
loss of muscle mass due to elderly, musclemassloss

Health condition

sarcopenie en obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht, Human Biology
Source(s) of monetary or material Support: TIFood and Nutrition

Intervention

Keyword: elderly, GH, GHRH + ARG, protein

Outcome measures

Primary outcome

The main endpoint of the study is the GH-concentration after ingestion of

placebo and protein. This is determined by blood-sampling.

Secondary outcome

The second study endpoint is the insulin-concentration after ingestion of

placebo and protein. This is determined by blood-sampling.

Another endpoint is the correlation between the effect of standard clinical

GHST and the protein-drink on GH-secretion.

Correlation between the amount of visceral fat mass (estimated with DXA) and

the GH concentrations after standard clinical GHST and protein-drink.

Study description

Background summary

Elderly and visceral obese persons are characterized by low GH-concentrations. GH is importent for maintanence of muscle mass and decrease in fat-mass (body composition) and is stimulated by intake of gelatin protein.

Study objective

To investigate if the GH-promoting effect of gelatine- protein is present in non-overweight and overweight elderly people.

Study design

Randomized cross-over design with 3 conditions.

Intervention

-GHRH+ARG-test: Test contains GHRH: GHRH1-29; (GEREF, Serono, Italy) is intravenous infused in an amount of 100µg/kg bodyweight after a 30 minute rest period. Serum growth hormone concentrations were measured at 0, 15, 30, 60, 90 and 120 minutes. Arginine hydrochloride (Fresenius Kabi Clayton Nederland), 30 gram intravenous infused over 30 min from 0 to 30 min, up to a maximum of 30 g. ARG infusion starts at the same time then GHRH infusion.

-Placebo: The placebo-test contains only water and sugarfree syrup. For the placebo test, subjects will arrive in the morning (08:00h) in fasted state, they are instructed to drink and eat nothing after 22:00h the day before the testday and limit their physical activity the day before the tests (no sport). At 8:30h, subjects receive a drink, which contains 500 ml water and 8 lemon drops. Blood samples are taken every 20 minutes for 300 minutes to measure growth hormone levels.

-Protein-drink: In this test subjects receive a protein drink, containing complete soy protein, solved in water with 8 lemon drops. Soy protein is a dietary protein, containing relatively high levels of arginine and has been shown in our preceding studies to be a more potent GH stimulator in adult women compared with an amino acid solution containing arginine[6].
For the protein test, subjects will arrive in the morning (08:00h) in fasted state, they are instructed to drink and eat nothing after 22:00h the day before the testday and limit their physical activity the day before the tests (no sport). At 8:30 h, subjects receive a drink, which contains 0.6gram per kg bodyweight. Blood samples are taken every 20 minutes for 300 minutes to measure growth hormone levels.

-DXA-scan to estimate the amount of visceral fat mass

Study burden and risks

This research is neither beneficial nor harmful to the subjects. Allergy reactions on soy protein are possible, but in the screening, test persons with a known allergy for soy are excluded. The possible side-effect of the GHRH are hot-flushes and thereby an increased blood pressure and hart-rate for a short time. Possible side-effects of ARG are nausea and vomiting. There are no further risks for the subjects in undergoing the standard clinical GHRH+ARG-test or in consuming the test-drink, as the GHRH+ARG-test is a standard clinical test, using in hospitals to determine GHDeficiency and the protein used are food-proof and present in our daily diet.
The blood sampling in this study does not include any other risks for the subjects, apart from its usual risk of minor bruising.

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

women, post-menopausal, age between 55-65, 8 visceral obese (BMI 27-33 and Waist/hip-ratio>0.85), 8 normal weight (BMI20-25, wasit/hip<0.85)

Exclusion criteria

Use of medication, instabel weight, disorders as cardiovascular diseases, diabetics, cancer, gelatin-allergic

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2008
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-08-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-11-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL21516.068.08