Acute effects of growth hormone on cognitive functioning and related brain physiology in healthy subjects

Published: 27-10-2008
Last updated: 11-05-2024

We will evaluate the acute effects of GH on, and its relation with, cognition in healthy subjects. The present proposal focuses on the following questions:1. Does an acute rise of plasma GH levels have a (beneficial) effect on cognitive performance...

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

Summary

ID

NL-OMON35220

Source
ToetsingOnline

Brief title
Acute effects of growth hormone

Condition

- Other condition
- Hypothalamus and pituitary gland disorders

Synonym
Growth Hormone Deficiency (GHD), the effect of growth hormone

Health condition

veroudering

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cognition, Cognitive functioning, ERP (EEG), Growth Hormone (GH), Quality of Life (QoL)

Outcome measures

Primary outcome

The correlation between GH and cognitive functioning, and related brain

physiology in healthy subjects.

Secondary outcome

The correlation between cortisol/ testosterone and cognitive functioning, and

related brain physiology in healthy subjects.

Study description

Background summary

Growth hormone (GH) receptors are found in the brain itself, and GH and Insulin-like growth factor-1 (IGF-1) can cross the blood brain barrier, Several studies have demonstrated a relationship between GH status (GH deficiency, lower GH levels in elderly subjects) and specific cognitive functions, but no data exist regarding acute effects of GH on cognition. The present study proposal focuses on the acute effect of GH on cognition.

Study objective

We will evaluate the acute effects of GH on, and its relation with, cognition in healthy subjects.
The present proposal focuses on the following questions:
1. Does an acute rise of plasma GH levels have a (beneficial) effect on cognitive performance in healthy subjects?
2. Is GH (directly) associated with cognitive function in healthy subjects?

Study design

Double-blind randomized placebo-controlled acute intervention study on two separate days.

Intervention

One intravenous injection with either GH releasing hormone (GHRH) or placebo.

Study burden and risks

The burden to the study subjects is the insertion of an intravenous catheter, the injection of GHRH, blood sampling (7 x), the performance of neuropsychological tests and registration of ERPs. The subjects will be studied twice, each study day approximately 5 hours. There are no benefits. Study subjects are healthy controls.

Contacts

Public
Universiteit Utrecht

Heidelberglaan 2
3584 CS, Utrecht
NL
Scientific
Universiteit Utrecht

Heidelberglaan 2
3584 CS, Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- male
- age; older than 55 years old
- BMI between 20 & 33

Exclusion criteria

1. Any history of malignant disease.
2. Any history of pituitary or hypothalamic disease.
3. Any history of other central neurological disorders, including cerebrovascular infarctions, Parkinson's disease, multiple sclerosis, Alzheimer's disease.
4. Any active or recent (< 5years) psychiatric disease, including manic and depressive disorders or schizophrenia.
5. Severe cognitive deficits leading to incapacity to live independently.
6. Severe loss of vision (vision should be at least 0.5 in one eye), which is not corrected for (by glasses or lenses).
7. Any other internal condition necessitating chronic medication (subjects with well controlled hypertension, stable thyroid hormone substitution, stable hyperlipidaemia, osteoporosis, or chronic obstructive lung disease not necessitating systemic corticosteroids may be included; specific other situations can be judged by the researchers).
8. Alcohol consumption > 4 U/day.
9. Use of drugs (cannabis, cocaine, amphetamines etc.).
10. Use of medication that might affect cognitive function (e.g. benzodiazepines, antidepressants, antiepileptics, etc.).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-06-2009
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	somatorelineacetaat-hydraat
Generic name:	Growth Hormone Releasing Hormone (GHRH) Ferring
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	27-10-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-01-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-03-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2008-005494-35-NL
CCMO	NL22957.041.08