individueel setpoint Hypothalamus Hypofyse Gonade as bij de man; een pilotstudy

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To study whether there is an individual setpoint for the hypothalamus-pituitary-gonad axis in men

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine disorders of gonadal function
Study type	Interventional

Summary

ID

NL-OMON30596

Source
ToetsingOnline

Brief title
individual setpoint hypothalamus pituitary gonad axis in men, a pilotstudy

Condition

- Endocrine disorders of gonadal function

Synonym
androgen deficiency, hypogonadism

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: researchbudget endocrinologie

Intervention

Keyword: HPG axis, ketoconazole, male

Outcome measures

Primary outcome

levels of total testosterone and 17-OH-progesterone before and during

ketoconazole use and after application of human chorionic gonadotropin

Secondary outcome

not applicable

Study description

Background summary

In men testosterone (T) production takes place in the testes under the stimulating influence of pituitary derived luiteinzing hormone (LH). LH is stimulated by the pulsatile relaese of gonadotropin releasing hormone (GnRH) by the hypothalamus.
LH and GnRH release are inhibited by circulating testosterone. The intraindividual variation of the testosterone concentration appears to be much smaller than the interindividual variation. From this one may conclude that every man has a individual setpoint for the regulation of the hypothalamus-pituitary-gonad axis.

Study objective

To study whether there is an individual setpoint for the hypothalamus-pituitary-gonad axis in men

Study design

open lable intervention

Intervention

ketoconazole 4 times 100 mg daily for 9 days.
human chorionic gonadotropin 5000 IE once.

Study burden and risks

18 x venepuncture, on days 1, 8 and 15 blood is drawn via a intravenous catheter (total 250 ml)
possible side effects of ketoconazole: gastrointestinal complaints, headache, vertigo, exanthema, pruritis, transient increase of liver enzymes. The chances of having side effects is small when ketoconazole is adminstered for less that 14 days. For safety reasons liver enzymes will be tested after 5 days of ketoconazole use and when liver enzyms increase more than two times the upper refence limit the subject will be withdrawn from the study.

Contacts

Public
Vrije Universiteit Medisch Centrum

postbus 7057
1007 mb
Nederland
Scientific
Vrije Universiteit Medisch Centrum

postbus 7057
1007 mb
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

male, age 18-40 years, healthy

Exclusion criteria

intolerability of ketoconazole, use of testosterone, aldactone, finasteride, estradiol. Elevated liver enzymes, hypogonadism (T<10 nmol/l, LH > 8 IU/l), elevated estradiol level (>250 pmol/l)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2007
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

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
CCMO	NL15788.029.07