Correlation between salivary testosterone and free testosterone

Published: 20-01-2010
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To study the correlation between salivary T and (measured and calculated) serum free T.

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

Summary

ID

NL-OMON34959

Source
ToetsingOnline

Brief title
Salivary testosterone

Condition

- Endocrine disorders of gonadal function

Synonym
niet van toepassing

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Research budget afdeling Klinische Chemie

Intervention

Keyword: diagnostics, LC-MS/MS, testosterone

Outcome measures

Primary outcome

concentration of testosterone in saliva and free testosterone concentration in

serum

Secondary outcome

not applicable

Study description

Background summary

Free testosterone (fT) levels reflect the physiological actions of the hormone. However, determination of free testosterone concentrations is cumbersome. So for diagnostics purposes total testosterone (tT) in serum is measured as a substitute. An alternative is salivary T, which is believed to reflect the fT concentration. Saliva measurements have great advantages: sample collection is minimally invasive and a practical alternative for (sequential) measurements of serum testosterone. Recent technical developments enables us to measure T in different matrices with great sensitivity and in small sample volumes. A salivary and a serum T assay has been developed using liquid chromatography * tandem mass spectrometry (LC-MS/MS) to investigate the correlation between fT and salivary T, so that salivary T can be assessed in future studies.

Study objective

To study the correlation between salivary T and (measured and calculated) serum free T.

Study design

The levels of testosteron in saliva and (measured and calculated) serum free testosterone will be compared.

Study burden and risks

One blood sample via venapucture and one saliva sample will be taken from experimental subjects.

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

age >18 yrs

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-03-2010
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	20-01-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	13-04-2010
Application type:	Amendment
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	NL30102.029.09