Nerve Growth Factor β validation study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25927

Source
Nationaal Trial Register

Health condition

Nerve growth factor β
Healty volunteers

Sponsors and support

Primary sponsor: VU University Medical Center, Amsterdam
Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

The main study parameters will be the correlation between the DBS and saliva methods compared to venous blood sampling. In order to do so, NGF-β concentrations (pg/ml) for each method will be measured. The difference between saliva testing and venous blood and the difference between dried blood spot and venous blood will be calculated.

Secondary outcome

In the informed consent volunteers are asked for their permission to use stored samples to measure other reproduction related hormones.

Study description

Background summary

Rationale: There are roughly two types of ovulation: spontaneous and induced. Copulation is the speculated mechanism behind induced ovulation. The ovulation induction substance in semen has been identified as nerve growth factor β (NGF-β). In animal studies, semen plasma derived NGF-β indeed has an effect on female ovulation, follicle development and a luteotropic effect. The role of NGF-β on human ovulation has never been studied. It is known that NGF-β plays an important role in many different types of human tissue, for instance the nervous system and immune system. All studies use venous blood to measure the NGF-β concentration. However, in order to study the effect of NGF-β on human ovulation, multiple serial measurements are needed, ideally immediately before and after natural intercourse. Therefore, a patient-friendly and minimally interrupting method is necessary. Serial dried blood spot analysis and saliva sample testing are potential methods, but both are not validated for NGF-β yet. The aim of this study will be to do a method comparison study, to validate the use of both methods compared to venous blood for NGF-β.

Objective: To answer the question if dried blood spot (DBS) analysis and saliva testing are reliable methods to determine the concentration of NGF-ß in healthy subjects.

Study design: Cross sectional method comparison validation study.

Study population: Healthy human volunteers of reproductive age (18 – 43 years).

Main study parameters/endpoints: The main study parameters are the correlation and limits of agreement between dried blood spots/saliva samples compared to venous blood concentration.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The procedure for participants includes one hospital visit or home visit for saliva,

dried blood spot and venous blood sampling and a questionnaire has to be completed. There will be no extra risks nor benefits for the participants. The risk analysis for this study concluded the risk for (serious) adverse events is negligible.

Study objective

Dried blood spot analysis is a reliable method to measure Nerve Growth Factor β.

Study design

Questionaire will be completed at home, before the first visit. During the first visit, all samples will be collected. Afterwards all samples will be analyzed.

Intervention

Questionaire, saliva sampling, serum sampling, dried blood spot collection.

Contacts

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Eligibility criteria

Inclusion criteria

- Both male and female volunteers.

- 18 years or older.

- Willingness to give informed consent, to donate venous blood, dried blood spots obtained through a finger puncture, saliva and complete a questionnaire.

- Sufficient command of Dutch or English language and capable of understanding participants information.

Exclusion criteria

- Contraindications for donating blood (phlebitis, dermatitis, psoriasis, lymphedema, arterial venous fistula, hematoma on or around insert place, mamma-amputation or axillary dissection of lymph nodes).

- Age younger than 18 years.

- Poor dental condition.

- Volunteers who brushed their teeth within 45 minutes prior to sample collection.

- Volunteers who had dental work within 24 hours prior to sample collection.

- Volunteers who had their last meal, sigarette, or drank anything except for water within 60 minutes prior to sample collection.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	07-02-2018
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-01-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44502
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6804
NTR-old	NTR6990
CCMO	NL63048.029.17
OMON	NL-OMON44502

Study results