# NERVE GROWTH FACTOR * MEASUREMENT METHOD VALIDATION STUDY: DRIED BLOOD SPOT ANALYSIS AND SALIVA SAMPLE TESTING COMPARED TO VENOUS SERUM CONCENTRATION

Published: 15-01-2018
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To answer the question if dried blood spot (DBS) analysis and saliva hormone testing are reliable methods to determine the concentration of NGF-ß in healthy subjects.

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Other condition |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON44502

**Source**
ToetsingOnline

**Brief title**
NGF * validation study

### Condition

- Other condition
- Gonadotrophin and sex hormone changes

**Synonym**
nerve growth factor, nerve growth factor 

**Health condition**

valideren van diagnostische testen

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Dried blood spots, Nerve growth factor □, Saliva, Validation study

## Outcome measures

### Primary outcome

The main study parameters are the correlation and limits of agreement between

dried blood spots/saliva samples compared to venous blood concentration.

### Secondary outcome

not applicable

# Study description

### Background summary

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 * (NGF-*). In animal studies, semen plasma derived NGF-* indeed has an effect on female ovulation, follicle development and a luteotropic effect. The role of NGF-* on human ovulation has never been studied. It is known that NGF-* 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-* concentration. However, in order to study the effect of NGF-* 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-* 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-*.

### Study objective

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

### Study design

Cross sectional method comparison validation study.

### Study burden and risks

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.

## 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

Healthy female and male participants, 18 years or older, who are willing to give informed consent, have sufficient command of Dutch or English language and are 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)
- Poor dental condition
- Age <18 years
- Volunteers who brushed their teeth within 45 minutes prior to saliva sample collection.
- Volunteers who had dental work within 24 hours prior to saliva sample collection.
- Volunteers who had their last meal, or drank anything except for water within 60 minutes prior to saliva sample collection.

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 20-12-2017 |
| Enrollment: | 60 |

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| Type: | Anticipated |

## Ethics review

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|---|---|
| Approved WMO Date: | 15-01-2018 |
| 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

ID: 25927
Source: Nationaal Trial Register
Title:

### In other registers

| Register | ID |
|---|---|
| CCMO | NL63048.029.17 |
| OMON | NL-OMON25927 |