# Oxidative stRess drIver Of male iNfertility: ORION study

Published: 26-11-2020
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To address the role of free thiols in males of couples seeking infertility treatment.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Reproductive tract disorders NEC |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON49093

**Source**
ToetsingOnline

**Brief title**
ORION study

### Condition

- Reproductive tract disorders NEC

**Synonym**
male infertility

**Research involving**
Human

### Sponsors and support

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

### Intervention

**Keyword:** free thiols, lifestyle, male infertility, oxidative stress

## Outcome measures

### Primary outcome

The main study parameter will be free thiols in patients with

oligo-asthenospermia and patients with normospermia.

### Secondary outcome

Concomitant measurable antioxidants.

General health parameters:

- BMI

- Comorbidities

- Medication

- Level of degree

Lifestyle parameters:

- Diet

- Physical activity

- Smoking

- Illicit drug use

- Toxic exposure at work

# Study description

### Background summary

Human cells use oxygen to survive and thus produce free radicals (FR). Oxidative stress (OS) occurs when reactive oxygen species (ROS) production exceeds the cell damage defense system. Elevated ROS levels, due to various endogenous and exogenous factors are associated with a reduced fertilizing

capacity of spermatozoa.
Free thiols are readily oxidized by oxygen and sulfur species and their circulating level may directly reflect the systemic redox status. In males with oligo-asthenospermia it is thought that the systemic redox status is different compared to males with a normospermia. This might be of interest regarding a potential target for therapy.

### Study objective

To address the role of free thiols in males of couples seeking infertility treatment.

### Study design

Exploratory cross-sectional pilot study.

### Study burden and risks

There will be no direct benefit for the participating males, other than the perspective of the feeling to contribute to extending the knowledge on male infertility. After informed consent a questionnaire will be taken by telephone and a single blood sample will be withdrawn on the day of semen analysis, preventing an extra visit to the hospital.

## 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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
males of couples visiting the Center of Reproductive medicine at the UMCG between 18-55 years old.

### Exclusion criteria

* Males who receive(d) chemo- and/or radiotherapy, use(d) testosterone suppletion and/or anabolic steroids
* Males who have an abnormal SA due to genetic causes.
* Semen analysis with round cells >2x106 /ml (as marker for infection)

## Study design

### Design

**Study type:** Observational invasive

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 05-01-2021 |

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|---|---|
| Enrollment: | 40 |
| Type: | Actual |

## Ethics review

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|---|---|
| Approved WMO Date: | 26-11-2020 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

## 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 | NL75634.042.20 |