MeaSuring free radicals with diamond magnetometRy In hUman single Sperm cells related to microbiota and lifestyle factors: SIRIUS study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Sexual function and fertility disorders
Study type	Observational invasive

Summary

ID

NL-OMON52347

Source ToetsingOnline

Brief title SIRIUS study

Condition

• Sexual function and fertility disorders

Synonym male infertility

Research involving Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

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Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: lifestyle, male infertility, microbiota, nano-diamond technique

Outcome measures

Primary outcome

The main study parameters will be free radical concentration in seminal plasma

and at sperm cells correlated with microbiota in semen plasma and related to

standard semen-parameters, malondialdehyde (MDA) en free thiols in bloof serum

lifestyle factors and food intake.

Secondary outcome

na.

Study description

Background summary

To date, 15% of couples experience issues with fertility and in 40-50% of the cases this is due to fertility issues in men. Reactive oxygen species (ROS) and especially free radicals (the most reactive ones) play a key role in fertilisation and sperm maturation. They are also believed to be a major contributor to infertility. The free radical theory of infertility states that damage by free radicals is a main cause of infertility in males. Despite their physiological and pathophysiological relevance, they are not used as diagnostic biomarkers in daily practice or as target for therapeutics. Currently, it is unknown where and when the free radicals are generated exactly due to a lack of proper detection techniques. Therefore, a new technique will be utilized called diamond magnetometry which allows nanoscale magnetic resonance measurements (Mamin 2013). This guantum sensing technique is uniquely sensitive and allows real-time single cell measurements with sub-cellular resolution. Unlike most other techniques this method is specific for free radicals. Furthermore, it is not known which factors influence the free radical generation e.g. lifestyle and food intake, and whether this radical generation in semen plasma is a reflection of systemic radical levels.

Recently, it has been shown that human semen may host a specific microbiota

although the origin of semen microbiota is unknown. The reason to focus on microbiota is that they have been suggested to play a role in the context of reproduction [Baud 2019, Hou 2013, Weng 2014]. While several studies have been carried out focusing on the female reproductive system, less is known about male microbiota and its influence on fertility (Tomaiuolo 2020). Although a direct link between fertility and microbiota remains to be established, alterations of the diversity of a seminal microbiota have been associated with an altered morphology and motility of sperm cells (Baud et al. 2019). The molecular processes through which bacteria would be able to alter semen quality are unknown.

Study objective

We hypothesize that one possible mechanism may involve the free radical formation. Therefore, measuring free radical generation will be correlated to the diversity of seminal microbiota and related with semen-parameters defined by the WHO guidelines, lifestyle factors and food intake.

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. Semen collection is part of standard care. No extra semen samples will be collected for this study. After informed consent, a food frequency questionnaire (FFQ) will be forwarded electronically and a single blood sample will be withdrawn on the day of semen collection, preventing an extra visit to the hospital. 20 participants will be asked to take a swab of the skin of the glans penis serving as a control for the commensal flora.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years)

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 CRM at the UMCG between 18-55 years old.
- Planned semen-analysis as standard care.

Exclusion criteria

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

Study design

Design

Study type:Observational invasiveMasking:Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	03-07-2024
Enrollment:	80
Туре:	Actual

Ethics review

Approved WMO	
Date:	17-11-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	15-03-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	27-08-2024
Application type:	Amendment
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.

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In other registers

Register

ССМО

ID NL78280.042.21