

WAVES studie

No registrations found.

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

Summary

ID

NL-OMON29437

Source

NTR

Health condition

Subfertility, IVF, ART, uterine contractions

Sponsors and support

Primary sponsor: Catharina Ziekenhuis, Eindhoven

Source(s) of monetary or material Support: Funded by HTSM grant

Intervention

Outcome measures

Primary outcome

1. Test reliability of electrohysterographic and automated ultrasound for assessing uterine contractions during different phases of the normal menstrual cycle in a prospective selected cohort.
2. Determine objective changes in electric activity and subsequent endometrial wave patterns in relation to phase of menstrual cycle (characterization of waves).

Secondary outcome

1. Identification of prognostic features of electrohysterographic and automated ultrasound for

the

success rate of fertility treatment.

2. Identifying the role of sex-hormone blood levels in the characteristics of endometrial waves.

Study description

Background summary

Successful embryo implantation depends on multiple factors both embryonic and uterine. Uterine contractions (also called uterine peristalsis or uterine waves) play a role in this mechanism. Studies have shown that with monitoring and modulation of the contractions, pregnancy chances could improve. Yet, the lack of a reliable, objective and user-friendly tool to measure these contractions, hampers its use in daily practice. We think electrohysterography or automated ultrasound assessment might be the tool we need to optimally benefit from the knowledge we have of these uterine contractions and increase pregnancy rates in the future.

Study objective

We think it is possible to measure and characterize uterine contractions in a non-pregnant uterus, using electrohysterography (EHG).

Study design

Our goal is to finish Phase I and II in 2017 and Phase III in 2020.
Update 05-10-2018: Phases I, IIa, and IIb are completed. Phases IIIa and IIIb are in progress.
We expect their completion before August 2020.

Intervention

Simultaneous measurements with abdominal electrohysterography and transvaginal ultrasound.

Co-interventions:

In Phase IIa, IIIa and IIIb blood tests are performed to assess hormone levels (estradiol, progesterone, LH and FSH).

Contacts

Public

-
N.P.M. Kuijsters
[default]
The Netherlands

Scientific

-
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Eligibility criteria

Inclusion criteria

Phase I:

- Age 18-40 years
- Under hormonal fertility treatment

Phase IIa:

- Age ≥ 18 and premenopausal
- Regular, natural menstrual cycle

Phase IIb:

- Age ≥ 18 and premenopausal
- Indication for hysterectomy in near future

Phase IIIa:

- Age 18-40
- Regular, natural menstrual cycle

Phase IIIb:

- Age 18-40
- Under hormonal fertility treatment

Exclusion criteria

Phase I:

- Pregnancy
- Mental disability
- Significant language barrier
- Uterine anomalies (congenital or not congenital)
- Uterine pathologies (leiomyomas, adenomyosis, endometriosis)
- Caesarean section in the past

Phase IIa:

- Like in Phase I (Pregnancy, Mental disability, Significant language barrier, Uterine anomalies (congenital or not congenital), Uterine pathologies (leiomyomas, adenomyosis, endometriosis), Caesarean section in the past)
- Hormonal medication of any kind

Phase IIb:

- Like in Phase I

Phase IIIa:

- Exclusion criteria of Phase II
- Known infertility

Phase IIIb:

- Exclusion criteria of Phase I

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):	03-08-2015
Enrollment:	135
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 25-06-2015

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 53115

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5035
NTR-old	NTR5264
CCMO	NL52466.100.15
OMON	NL-OMON53115

Study results