

WAVES studie

Gepubliceerd: 25-06-2015 Laatste bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29437

Bron

NTR

Aandoening

Subfertility, IVF, ART, uterine contractions

Ondersteuning

Primaire sponsor: Catharina Ziekenhuis, Eindhoven

Overige ondersteuning: Funded by HTSM grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

-

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

-

Wetenschappelijk

-

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

-

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	03-08-2015

Aantal proefpersonen: 135
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 25-06-2015
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 53115
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten