Endometrial Waves and Fertility and Benign Uterine Disorders

Published: 21-08-2015
Last updated: 15-05-2024

Measurement and characterization of contractions in a non-pregnant uterus by noninvasive electrophysiological measurements of the uterine muscle activity using a small electrode matrix placed on the abdomen. Simultaneous vaginal ultrasonography...

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

Summary

ID

NL-OMON53115

Source
ToetsingOnline

Brief title
WAVES study

Condition

- Sexual function and fertility disorders

Synonym
Uterine contractions, uterine peristalsis

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Ferring,GE Healthcare,HTSM Grant ;Stichting Vrouw en Onderzoek,Samsung

Intervention

Keyword: Benign Uterine Disorders, Endometrial waves, Placental Remnants, Uterine contractions

Outcome measures

Primary outcome

1. reliability of the EHG 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).

3. Assess the influence of the vaginal microbiome on uterine peristalsis in

infertile and fertile women

Outcomes Phase IIc:

- Uterine contraction parameters (frequency, amplitude, coordination,

direction) pre and post hormonal therapy, and/or prior to embryo transfer

Outcomes Phase III:

- Uterine contraction parameters (frequency, amplitude, coordination,

direction) prior to placement/removal of IUDs or placental remnants

Secondary outcome

1. Identification of prognostic factors for fertility in relation to changes in

electric myometrial during the menstrual cycle.

2. Identifying the role of sex-hormone bloodlevels in the characteristics of

endometrial waves.

Study description

Background summary

In spite of major efforts to improve ART (assisted reproductive technology) over the past 20 years, the overall effectiveness remains below 25-30% per treatment cycle, even for IVF (in vitro fertilization) which is the most advanced technique. Most IVF failures remain unexplained. The emotional, social, and economical implications of a series of repeated IVF failures are tremendous.
There is significant evidence for major involvement of uterine contractions in IVF failure. Precise interventions on contractions are possible and might increase the success rate of IVF. Unfortunately, so far there is no method suitable for objective, complete, and continuous characterization of uterine activity during the normal ovulatory cycle.
Developing a method for continuous and objective assessment of uterine contraction characteristics is an essential step to boost IVF success rates. It would allow an understanding of the impact of contractions on IVF failure and would be a necessary prerequisite for tailoring specific treatments.

It is becoming generally accepted that women with benign uterine disorder most likely have aberrant uterine contractions. This could be an explanation for fertility issues and other symptoms in these women, however research is scarce. It is known that symptoms respond well to hormonal therapy, which may have something to do with changes in uterine contractions. If more was known if/how these contraction function these could be a potential aetiological mechanism and/or treatment target.

Furthermore, recent literature has suggested a potential effect of vaginal/uterine microbiome on uterine contractions. This is been little researched in IVF patients but is a trending topic, let alone being researched using an objective quantitative method.

Study objective

Measurement and characterization of contractions in a non-pregnant uterus by noninvasive electrophysiological measurements of the uterine muscle activity using a small electrode matrix placed on the abdomen. Simultaneous vaginal ultrasonography recordings will be performed.

Objectives Phase IIc:
Measurement and characterisation of uterine contraction via transvaginal

ultrasound in benign uterine disorders(adenomyosis, leiomyomas, congenital uterine anomalies), before and after hormonal treatment, and/or in the context of IVF

Phase III:
Measurement and characterisation of uterine contractions via transvaginal ultrasound in women with intrauterine IUDs or placental remnants prior to removal/placement.

Study design

An observational prospective study in a selected cohort

Study burden and risks

There are no risks associated with participation.

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623EJ
NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Phase I: Age 18-40 years, patients under hormonal fertility treatment
- Phase IIa: Age 18-40 years, healthy women with regular natural cycle.
- Phase IIb: Age >18 years, hysterectomy
- Phase IIc: Age 18-40 years, diagnosed with at least one of the following: adenomyosis, leiomyoma, uterine anomaly
- Optional: under hormonal fertility treatment in the context of IVF
- Phase III:
- Age 18-40 years
- Regular menstrual cycle
- Diagnosed with at least one of the following: adenomyosis, leiomyoma, (congenital) uterine anomaly, placental remnant AND/OR:
- Wish for intrauterine contraceptive device
- Under hormonal fertility treatment in the context of IVF

Exclusion criteria

General:
- Pregnancy
- Mental disability
- Significant language barrier

Phase Ia:
- Uterine anomalies (congenital or not congenital)
- Uterine pathologies (leiomyomas, adenomyosis, endometriosis)
- Cesarian section in the past, Phase IIa:
- Exclusion criteria of Phase I
- Hormonal medication of any kind,

Phase IIb:
- General + Phase I
- Phase IIc, III: General exclusion criteria

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-11-2015
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO Date:	21-08-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-01-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-04-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-07-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-09-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	23-03-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 29437
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL52466.100.15
OMON	NL-OMON29437