The effect of uterine bathing on implantation in endometriosis patients undergoing IVF/ICSI: a randomized controlled pilot trial

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To evaluate the effect of uterine bathing in improving the results of IVF/ICSI treatment in patients with endometriosis ASRM stage I-IV.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sexual function and fertility disorders
Study type	Interventional

Summary

ID

NL-OMON44836

Source
ToetsingOnline

Brief title
TUBIE trial

Condition

- Sexual function and fertility disorders

Synonym
Subfertile couples with an indication for IVF/ICSI treatment, Subfertility with indication for IVF/ICSI

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

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

Intervention

Keyword: Endometriosis, Implantation, IVF/ICSI, Uterine Bathing

Outcome measures

Primary outcome

Live birth rate after fresh embryo transfer.

Secondary outcome

Implantation rate, clinical pregnancy rate, ongoing pregnancy rate,

miscarriages rate, ectopic pregnancy rate, multiple pregnancy rate.

Study description

Background summary

In patients with endometriosis, IVF/ICSI ongoing pregnancy rates are decreased compared to patients without endometriosis. This could be the result of an impaired implantation due to an immunological altered endometrium. In endometriosis patients, uterine bathing with Lipiodol seems to improve IVF/ICSI pregnancy rates. The mechanism of this observed improvement is still unclear, but could be related to the mechanical pressure on the endometrium induced by intrauterine infusion of fluids. More invasively, local endometrial injury is shown to positively influence ongoing pregnancy rates in patients with recurrent implantation failure undergoing IVF/ICSI. This is probably based on the provocation of an inflammatory reaction, which stimulates endometrial regeneration and proliferation, which is necessary for successful implantation. To a lesser extent this might be induced by mechanical stress, which is a less invasive procedure than local endometrial injury. However, this has not been investigated yet in endometriosis patients.

Study objective

To evaluate the effect of uterine bathing in improving the results of IVF/ICSI treatment in patients with endometriosis ASRM stage I-IV.

Study design

Prospective randomized controlled pilot trial, parallel, two-arm study.

Intervention

Patients will be randomized to undergo uterine bathing through a GIS (intervention group) or a sham procedure (control group) before treatment with IVF/ICSI. The intervention will be performed in the *follicular phase* just before starting the GnRH analogue treatment (between the end of menses and cycle day 12).

Study burden and risks

A Gel Infusion Sonography (GIS) is routinely performed in patients during the fertility work up to rule out intracavitary pathology. During GIS some women experience minor discomfort in their lower abdomen. Furthermore bacteria in the vagina may enter the uterine cavity during GIS. This rarely happens, but if some bacteria enter the uterine cavity, this seldom leads to an intrauterine infection. Following a GIS procedure some patients will have light vaginal bleeding, which will cease within one or two days. All possible side effects and severe adverse events will be monitored and evaluated. The intervention will be performed at a routine visit, so there will be no more visits during participation. Since randomization is performed every participant has an equal chance to profit from possible benefits.

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

- Woman between 18 and 41 years old.
- Indication for IVF/ICSI (first, second or third attempt)
- Endometriosis ASRM stage I-IV
- Signed informed consent.

Exclusion criteria

- Women aged over 41 years
- Women who are unable to undergo IVF/ICSI
- Uterusanomalies (bicornis/didelphys/septa)
- Pregnancy
- Malignancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2014
Enrollment:	184
Type:	Actual

Medical products/devices used

Generic name:	Gel Infusion Sonography
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-04-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-09-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-03-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-07-2018

Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL46661.029.13