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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26775

Source
NTR

Brief title
TUBIE trial

Health condition

Subfertility, IVF/ICSI, implantation, Endometriosis.

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: VU University Medical Center

Intervention

Outcome measures

Primary outcome

Live birth rate after fresh embryo transfer

Secondary outcome

- Implantation rate, clinical pregnancy rate, ongoing pregnancy rate after fresh embryo transfer. - Multiple pregnancy, miscarriage and ectopic pregnancy rate after fresh embryo transfer. - Endometrial thickness at the day of Pregnyl®. - Adverse events defined as: intrauterine infection and severe bleeding after the intervention.

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. The purpose of this randomized controlled pilot study is to evaluate the effect of uterine bathing in improving the results of IVF/ICSI treatment in patients with endometriosis ASRM stage I-IV.

Interim Analysis
An interim analysis will be performed when 50% of the planned study population (92 of the planned total goal of 184 patients) has completed the study protocol and life birth rate (primary outcome) can be calculated. The purpose of this interim analysis is to assess the futility of this trial and to determine, based on the conditional power, whether early termination of the trial is inevitable when there is no evidence of a beneficial effect.

The critical value for the conditional power will be set at 90%. Observed absolute difference in percentage of life birth between arms needs to be at least 20-24% (depending on the exact proportions) for the trial to be continued. The interim analysis will be performed by an independent statistician who has no further involvement in this trial as unblinding is necessary in order to avoid continuation of the trial in case of a large difference between arms in favor of the control. Once the 50% study completion goal have been met, the outcomes of all study subjects who had completed the final study visit will be calculated. The final study visit is defined as the visit at which a negative treatment outcome was diagnosed or the date of delivery

Study objective

The primary hypothesis is that mechanical stress on the endometrium, induced by uterine bathing, results in higher live birth rates after IVF/ICSI treatment in patients with endometriosis (ASRM stage I-IV), compared to a placebo procedure.

Study design

- Ongoing pregnancy rate after fresh embryo (secondary outcome): Vital intrauterine pregnancy 12 weeks after embryo transfer.
– Live birth rate after fresh embryo transfer (primary outcome): Live birth 9 months after embryo transfer (questionnaire).

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 GIS will be performed by our local protocol. During the intervention a flexible catheter is placed beyond the ostium internum and will be connected to a syringe with approximately 10cc Gel, which will be infused in the uterine cavity. A transvaginal ultrasound will be made to check uterine distension. The Sham procedure is exactly performed like the GIS, with the exception of cervical insertion of the catheter. The catheter will be placed intravaginal. The intervention will be performed in the ‘luteal phase’ of the cycle preceding the IVF/ICSI treatment, on the same day the GnRH analogue treatment is started. After the procedure IVF/ICSI treatment will be continued according to our local protocol. Live birth rate after the first fresh embryo transfer will be our primary outcome. If patients are pregnant, after 9 months a questionnaire will be send to collect the data.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 18 and 41 years old
2. Undergoing IVF/ICSI treatment
3. Endometriosis ASRM stage I-IV

Exclusion criteria

1. Women aged over 41 years
2. Women who are unable to undergo IVF/ICSI treatment
3. Uterus anomalies (bicornis/didelphys/septa)
4. Pregnancy or malignancy
5. Not willing or able to sign the consent form
6. Previous participation in the trial

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2014
Enrollment:	184
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-10-2013
Application type:	First submission

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
NTR-new	NL4025
NTR-old	NTR4198
Other	METc VUmc : 2013.424
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A