Verhoogt ‘scratching’ van het baarmoederslijmvlies de kans op een spontane zwangerschap in paren met onverklaarde verminderde vruchtbaarheid en een spontane kans op zwangerschap van >30%?

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In up to 50% of subfertile couples infertility is diagnosed as being ‘unexplained’. Some of these couples may have an endometrial factor that negatively impacts implantation. It has been suggested that the chances of implantation after IVF are...

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22066

Source
Nationaal Trial Register

Brief title
SCRaTCH-OFO

Health condition

Unexplained subfertility, scratching, live birth, implantation, endometrium

Sponsors and support

Primary sponsor: UMC Utrecht
Trial executed within the NVOG-consortium 2.0
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Cumulative live birth rate (of which the ‘ongoing’ status should be achieved within 12 months after randomisation)

Secondary outcome

- Ongoing pregnancy rate
- Clinical pregnancy rate
- Miscarriage rate
- Twin birth rate
- Time to pregnancy
- Progression to IUI treatment
- Progression to IVF treatment
- Costs
- Endometrial tissue parameters in relation to reproductive succes or failure

Study description

Background summary

Hypothesis: In up to 50% of subfertile couples infertility is diagnosed as being ‘unexplained’. Some of these couples may have an endometrial factor that negatively impacts implantation. It has been suggested that the chances of implantation after IVF are increased by intentionally injuring (‘scratching’) the superficial lining of the womb. The inflammatory response will enable the endometrium to acquire a state of optimal receptivity thereby positively affecting live birth rates. Women with unexplained infertility following expectant management may also benefit from this scratching procedure.
Research question: Does endometrial scratching increase live birth rates in couples with unexplained infertility and a good prognosis (Hunault>30%)?
Study design: Randomized controlled non-blinded multi-center superiority trial with 12 months of follow-up
Study population Subfertile women who have completed their subfertility work-up and have a prognosis according to Hunault of > 30%.
Intervention: Endometrial scratch 6/7 days after the LH-surge
Comparison: No endometrial scratch
Main study outcomes: Cumulative live birth rate, Clinical pregnancy rate, Costs
Sample Size: Based on previous studies we expect the 12 month LBR to increase by 10% (35% in controls to 45% in scratch). To prove this superiority we will have to include 377

women in each arm to be able to detect this difference with a power of 80% (two-sided alpha 0.05). Anticipating 5% loss to follow up we need to include 792 women.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients who are randomized for endometrial scratching will pay one extra visit to the hospital. From existing literature it is clear that the rate and extent of adverse events is very low. The benefit is a potential increase in the chance to conceive for patients following expectant management.

Study objective

In up to 50% of subfertile couples infertility is diagnosed as being ‘unexplained’. Some of these couples may have an endometrial factor that negatively impacts implantation. It has been suggested that the chances of implantation after IVF are increased by intentionally injuring (‘scratching’) the superficial lining of the womb. The inflammatory response will enable the endometrium to acquire a state of optimal receptivity thereby positively affecting live birth rates. Women with unexplained infertility following expectant management may also benefit from this scratching procedure.

Study design

12 months of FU

Intervention

The scratch will be performed in a natural cycle with LH testing. The scratch will be performed 6 to 7 days after the positive LH test. If, for the individual patient, scheduling on this day is impossible then a scratch on day positive LH +5 or +8 is also okay. Women will receive instructions that they need to make sure that they are not pregnant in the scratch cycle (no sexual intercourse or sexual intercourse with appropriate contraceptive methods (e.g. oral contraception or condoms)). On the day of the scratch the gynecologist will verify if the woman has followed these instructions and only then will he/she start the procedure. The endometrial scratch will be performed by a maximum of 2 to 3 experienced and dedicated gynecologists per center. After exposing the uterine cervix and extensive cleaning with sterile water, the endometrial biopsy catheter will be gently introduced through the cervix up to the uterine fundus. The piston will then be drawn back to the end of the biopsy cannula, creating a negative pressure. To cover the entire endometrium, the examiner will apply a slow retraction of the device, while rotating the endometrial biopsy catheter over several ranges of 360 degrees. The procedure will be performed during 1-2 minutes. The obtained tissue will be snap-frozen in liquid nitrogen and transferred into a minimum of 3 FluidX tissue sample storage tubes (productnumber 68-4000) and stored at -80 degrees Celcius for later analysis. Each sample storage tube should be labelled with a unique label (which will be provided by the UMC Utrecht). A minimum block of 4mm tissue per tube should be stored.

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Eligibility criteria

Inclusion criteria

1. Diagnosis of Unexplained Infertility (UEI) and a Hunault of > 30%.
2. Female age 18-43 years
3. Primary or secondary infertility lasting at least 1 year
4. Regular menstrual cycle
5. Patent tubes (diagnosed by negative Chlamydia antibody titre and absence of risk factors for tubal disease, and/or hysterosalpingography or diagnostic laparoscopy)
6. Total motile sperm count > 3 million/ml
7. Normal transvaginal ultrasound, defined as no visible intracavitary pathology or intramural myomas with impression of the uterine cavity
8. Written informed consent

Exclusion criteria

1. History of lower abdominal or pelvic infection
2. Higher chance of intra-abdominal infection due to intestinal surgery (for for instance Crohn’s disease or colitis)
3. Endometriosis grade 3 and 4
4. Previous caesarean section with niche formation
5. The presence of untreated unilateral or bilateral hydrosalpinx
6. Recurrent miscarriage (defined as 2 or more pregnancy losses prior to 20 weeks of gestation)

7. Previous endometrial scratching
8. Meno-metrorrhagia (defined as any intermenstrual loss of blood)
9. Untreated/unsubstituted endocrine abnormalities (e.g. pituitary, thyroid, adrenal or pancreas)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-12-2017
Enrollment:	792
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 52881
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6498
NTR-old	NTR6687
Other	METC / ZonMW : 17-592/D / 843001808
CCMO	NL62675.041.17
OMON	NL-OMON52881

Study results