Continuous use of Oral contraceptives as an alternative for long term Pituitary down-regulation with a GnRH agonist prior to IVF/ICSI in Endometriosis patients: a randomised controlled trial

No registrations found.

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

Summary

ID

NL-OMON26777

Source
NTR

Brief title
COPIE trial

Health condition

Endometriosis, Assisted Reproductive Techniques, IVF, Pregnancy, Cost-Effectiveness, Subfertility, Infertility

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

Secondary outcomes are cumulative live birth rate after one IVF/ICSI treatment cycle including fresh and frozen embryo transfers up to 15 months after randomization, ongoing pregnancy rate, time to pregnancy, treatment outcome parameters (like number of oocytes), adverse events, complications, recurrences, quality of life, safety and costs effectiveness.

Study description

Background summary

In women suffering from endometriosis, long term pituitary down-regulation for three to six months prior to IVF/ICSI improves clinical pregnancy rates. However, discussion about this treatment strategy exist and uncomfortable side effects are often described. Alternatively, IVF/ICSI pre-treatment with continuously administered oral contraceptives may offer less side-effects, lower (in)direct costs as well as encouraging IVF outcomes in women with endometriosis. Until now, these two different IVF/ICSI pre-treatment strategies in women with severe endometriosis haven’t been directly compared yet. Therefore we planned an open-label, parallel two-arm randomized controlled trial to show a non-inferiority of continuous use of oral contraceptives versus long term pituitary down-regulation with a GnRH agonist prior to IVF/ICSI treatment in patients with severe endometriosis (ASRM stages III and IV).

Study objective

The continuous use of oral contraceptives for three months
prior to IVF/ICSI treatment will be non-inferior to the use of long term pituitary down-regulation with a GnRH agonist for three months prior to IVF/ICSI treatment in patients with severe endometriosis (ASRM stages III and IV).

Study design

Measurement will be performed at baseline and at three, six, nine, twelve and fifteen months after randomization.

Intervention

After informed consent, eligible women will be randomly allocated to the intervention group

(group 1; one-phase oral contraceptive (sub 50 pill) continuously during three subsequent months (i.e.3x28days)) or the reference group (group 2; three Leuprorelin 3.75mg i.m./s.c. depot injections during three subsequent months). Tibolon 2,5mg will be given daily as add back therapy in the reference group. After three months of pre-treatment the IVF/ICSI stimulation phase will be started.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients with presence of endometriosis (ASRM III-IV) confirmed by previous surgery or likely to be present based on TVUS or MRI (including presence of uni- or bilateral ovarian endometrioma and deep endometriosis).

- Scheduled for first, second or third IVF or ICSI treatment cycle

- Signed informed consent

Exclusion criteria

- Patients aged over 41 years (excluding patients from the day they have celebrated their 41

year birthday).

- Patients with known contraindications for oral contraceptives (history of VTE, positive family history for VTE and/or known thrombophilic abnormalities) or GnRH agonists.

- Patients who previously participated in this trial.

- Pregnancy.

- Pelvic inflammatory disease.

- Malignancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-11-2018
Enrollment:	300
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 55530
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5991
NTR-old	NTR6357
CCMO	NL59874.029.16
OMON	NL-OMON55530

Study results

Summary results
N.a.