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

Gepubliceerd: 16-03-2017 Laatst bijgewerkt: 19-03-2025

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...

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26777

Bron
NTR

Verkorte titel
COPIE trial

Aandoening

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

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: VU University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Live birth rate after fresh embryo transfer.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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).

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-11-2018
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55530
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N.a.