Treatment after six ovulatory cycles with clomiphene

Gepubliceerd: 16-09-2008 Laatst bijgewerkt: 18-08-2022

Gonadotropins after 5-7 ovulatory cycles with CC will lead to more multiple gestations and higher costs compared with extended CC treatment. Combination of CC or gonadotropins with IUI may result in a higher pregnancy rate.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26323

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Subfertile women with WHO class II anovulation who are ovulatory on CC, but have not conceived in 6 ovulatory cycles.

Ondersteuning

Primaire sponsor: Marleen J Nahuis
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome will be pregnancies leading to live birth.

Toelichting onderzoek

Achtergrond van het onderzoek

Ovulation induction with Clomiphene citrate (CC) is the first line treatment in subfertile women with WHO class II anovulation. Whereas almost 80% of these patients ovulate after CC, only 40 to 50% conceive. When unsuccessful in conception, treatment can be proceeded with gonadotropins. CC treatment is associated with a 8% risk of multiple gestation, whereas treatment with gonadotropins is associated with a risk of 30-40 %. At present, it is unclear for how many cycles ovulation induction with CC should be repeated. Alternatives are a switch to ovulation induction with gonadotropins and/or addition of intra-uterine insemination.

Doel van het onderzoek

Gonadotropins after 5-7 ovulatory cycles with CC will lead to more multiple gestations and higher costs compared with extended CC treatment.

Combination of CC or gonadotropins with IUI may result in a higher pregnancy rate.

Onderzoeksopzet

Preganacy or end of the study after 6 months.

Onderzoeksproduct en/of interventie

To study the effectiveness of the following interventions in patients who have not conceived after 5 to 7 ovulatory cycles with CC treatment

1. Extended CC treatment

2. Extended CC treatment combined with IUI

3. Gonadotropins

4. Gonadotropins combined with IUI.

Contactpersonen

Publiek

Medisch Spectrum Twente
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Wetenschappelijk

Medisch Spectrum Twente
Locatie Enschede Ariënsplein

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with five to seven ovulatory cycles after CC treatment and no conception. Ovulation is assessed by a midluteal progesterone (> 16 nmol/l), basal temperature curve, detection of LH surge or history.

2. All patients have normal serum FSH (<10 IU/l), E2 (> 80 pmol/l), prolactin (0,05 – 0,80 IU/l) and thyroid-stimulating hormone (0,4 - 4,0 mU/l).

3. All women have patent Fallopian tubes, proven by hysterosalpingography (HSG), a negative Chlamydia antibody titre (CAT) or diagnostic laparoscopy combined with tubal testing (DLS and TT).

4. The partners have normal semen parameters according to the modified criteria of the World Health Organization (1999).

5. Age between 18 and 40 years.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Patients who have previously been treated with gonadotropins or IVF are excluded.

2. Patients are excluded if they have intolerable symptoms when treated with CC like hot flashes affecting daily function, headaches, vision changes, and depression.

3. Patients are excluded if they are remaining anovulatory on CC 150 mg.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2008
Aantal proefpersonen:	660
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	16-09-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1389
NTR-old	NTR1449
Ander register	METC : P08-037
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten