Treatment after six ovulatory cycles with clomiphene

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26323

Source
Nationaal Trial Register

Brief title
N/A

Health condition

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

Sponsors and support

Primary sponsor: Marleen J Nahuis
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

The primary outcome will be pregnancies leading to live birth.

Secondary outcome

Secondary outcomes will be:
- clinical pregnancy
- miscarriage
- multiple pregnancy
- occurrence of ovulation
- ongoing pregnancy

Study description

Background summary

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.

Study objective

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.

Study design

Preganacy or end of the study after 6 months.

Intervention

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.

Contacts

Public
Medisch Spectrum Twente
Locatie Enschede Ariënsplein

Marleen J Nahuis
Ariensplein 1

Enschede 7511 JX
The Netherlands
+31 (0)53 4872330
Scientific
Medisch Spectrum Twente
Locatie Enschede Ariënsplein

Marleen J Nahuis
Ariensplein 1

Enschede 7511 JX
The Netherlands
+31 (0)53 4872330

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2008
Enrollment:	660
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	16-09-2008
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	NL1389
NTR-old	NTR1449
Other	METC : P08-037
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results