Postcoital testing in anovulatory women.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24105

Source
NTR

Brief title
N/A

Health condition

anovulatory WHO class II women, ovulatory with clomiphene citrate.

Sponsors and support

Primary sponsor: Medisch Spectrum Twente Enschede

Academisch Medisch Centrum Amsterdam

Vrije Universiteit Medisch Centrum Amsterdam
Source(s) of monetary or material Support: Medisch Spectrum Twente Enschede

Academisch Medisch Centrum Amsterdam

Vrije Universiteit Medisch Centrum Amsterdam

Intervention

Outcome measures

Primary outcome

The primary outcome measure is the occurrence of an ongoing, vital intra-uterine singleton pregnancy. An ongoing, vital pregnancy is defined as fetal heart beat seen by transvaginal ultrasonography at 12 weeks gestation. If no pregnancy occurs, follow-up ends after the sixth cycle.

Secondary outcome

1. Positive pregnancy test;

2. Occurrence of ovulation;

3. Total number of postcoital tests performed;

4. Median time to pregnancy;

5. Clinical pregnancy, defined as any registered heart beat at sonography;

6. Miscarriage, defined as loss of an intra uterine pregnancy (confirmed by ultrasound or histologic examination) before the 20th week of pregnancy;

7. Multiple pregnancy, defined as a registered heart beat of at least two fetuses at 12 weeks of gestation.

Study description

Background summary

Objective:

To determine the value of a post coital test (PCT) in the basic fertility work up in WHO class II subfertile women ovulatory after clomiphene citrate (CC).

Design:

A prospective follow up study.

Patients:

Patients with a history of subfertility and WHO class II anovulation, with normal prolactin (PRL) and thyroid stimulating hormone (TSH) levels, ovulatory after clomiphene citrate.

Inclusion criteria:

1. Age > 18 years;

2. Ovulation after incremental CC doses from 50 to 150 mg starting on day 3-5 for 5 days;

3. Partner with a total motile sperm count above 1 million.

Exclusion criteria:

1. Abnormal PRL or TSH value;

2. Known bilateral tubal pathology.

Intervention:

A basic fertility work up including a PCT.

Main outcome measure:

Pregnancy rates in women with a positive PCT compared to pregnancy rates in women with a negative PCT within a time horizon of six months.

Study objective

Pregnancy rates will not differ between patients with a positive and negative result of the PCT.

Study design

At the pereformance of the postcoital test and after six months.

Intervention

At least one PCT is performed during the basic fertility work-up. The test should be planned based on the basal body temperature (BBT) curve, ultrasound findings or cycle history. In couples where the timing depends on the BBT and cycle length, the PCT is scheduled the day before the expected ovulation. In cases where the timing depends on ultrasound findings, the PCT is performed once the dominant follicle is ¡Ý 18 mm. The couple is asked to have intercourse before the appointment. The PCT is performed by cleaning the cervix, followed by suction of endocervical mucus using a 1 ml disposable syringe. Clarity and spinnbarkeit are

assessed aiming for an optimal length of ¡Ý 7 cm. The PCT is judged to be normal if at least one progressive motile spermatozoon is seen in one of five high power fields at 400x magnification. All other PCT results are considered to be abnormal. If progressive motile spermatozoa are absent the test is scheduled again two days later or following the confirmation of a dominant follicle on ultrasound.

Contacts

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Eligibility criteria

Inclusion criteria

1. WHO class II anovulatory women who ovulate following use of incremental CC doses from 50 to 150 mg starting on dag 3-5 following 5 days of the cycle;

2. All patients have normal serum prolactin (0,05 ¨C 0,80 IU/l) and thyroid-stimulating hormone (0,4 - 4,0 mU/l);

3. Age > 18 years;

4. A partner with total motile sperm count above 1 million, according to the modified criteria of the World Health Organization (1999).

Exclusion criteria

1. Women who remain anovulatory on CC 150 mg or who become anovulatory after initial ovulation;

2. Known bilateral tubal obstruction.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2009
Enrollment:	250
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-03-2009
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	NL1618
NTR-old	NTR1702
Other	: P09-03
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A