

The postcoital test in WHO class II anovulatory women; useful or redundant? a prospective follow up study

Published: 01-04-2009

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sexual function and fertility disorders
Study type	Observational invasive

Summary

ID

NL-OMON36839

Source

ToetsingOnline

Brief title

postcoital test and anovulation

Condition

- Sexual function and fertility disorders

Synonym

anovulation, postcoital test

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anovulation, clomiphene citrate, postcoital testing

Outcome measures

Primary outcome

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

Secondary outcome

- Positive pregnancy test
- occurrence of ovulation
- total number of postcoital tests performed
- median time to pregnancy in the two groups.
- clinical pregnancy, defined as any registered heart beat at sonography
- miscarriage, defined as loss of an intra uterine pregnancy (confirmed by ultrasound or histologic examination) before the 20th week of pregnancy.
- multiple pregnancy, defined as a registered heart beat of at least two fetuses at 12 weeks of gestation
- costs

Study description

Background summary

High quality studies randomized or non randomized, in which the predictive value or the additional benefit of treatment with a negative PCT in WHO class II patients ovulatory on CC are lacking. In the guidelines from the Dutch society for Obstetrics and Gynecology, the PCT is mentioned among the care for couple with subfertility. However the guideline is unspecific about the interpretation of the PCT in relation to subsequent management.

In view of this lack of knowledge, we decided to evaluate whether a post coital test should be performed among WHO class II anovulatory patients who became ovulatory after treatment with CC.

Study objective

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

Study design

A prospective follow up study.

Study burden and risks

no additional risk.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- WHO class II anovulatory women who ovulate following use of incremental CC doses from 50-150 mg starting on day 3-5 during 5 days of the cycle.
- normal serum prolactin (0,05 - 0,80 IU/l, and TSH (0,4-4,0 mU/l
- age 18 years or older
- total motial sperm count above 1 million, according the modified criteria of the WHO

Exclusion criteria

- anovulatory on CC 150 mg / day
- known bilateral tubel pathology

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-06-2009

Enrollment: 250

Type: Actual

Ethics review

Approved WMO

Date:	01-04-2009
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO	
Date:	15-12-2011
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO	
Date:	02-01-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
CCMO	NL27135.044.09
Other	NTR