Is endometrial withdrawal bleeding necessary prior to ovulation induction with clomiphene citrate?;A randomized controlled trial and feasibility study

Published: 29-04-2016
Last updated: 20-04-2024

To evaluate the effects of withholding progesterone-induced endometrial withdrawal bleeding before ovulation induction on the time to pregnancy and the ongoing pregnancy rate.

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

Summary

ID

NL-OMON43480

Source
ToetsingOnline

Brief title
Stair Step Study

Condition

- Sexual function and fertility disorders

Synonym
PCOS/non-PCOS, WHO 2 ovulation disorders

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: clomiphene citrate, ovulation induction, withdrawal bleeding

Outcome measures

Primary outcome

The primary endpoints are the time to pregnancy and ongoing pregnancy rate

within a treatment horizon of 3 cycles.

Secondary outcome

Secondary endpoints include time to ovulation, endometrial thickness, multiple

pregnancy and the incidence of treatment failure.

Study description

Background summary

There is some information suggesting that a progesterone-induced withdrawal bleeding before the start of ovulation induction in women suffering from oligo- or amenorrhea reduces pregnancy and live birth rate.

Study objective

To evaluate the effects of withholding progesterone-induced endometrial withdrawal bleeding before ovulation induction on the time to pregnancy and the ongoing pregnancy rate.

Study design

Prospective multicenter randomized controlled feasibility study

Intervention

Patients will be randomized to receive one of the following two treatments:
Stair step group: blind start ovulation induction (no progesterone induced withdrawal bleeding and stair step protocol in case of treatment failure.
Control: standard care; a progesterone induced withdrawal bleeding in case of no spontaneous menses before starting an ovulation induction cycle and in

between anovulatory cycles.

Study burden and risks

The number of site visits or physical examinations will not differ from accepted clinical practice.

Contacts

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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 classification category 2 PCOS or non-PCOS
Age between 18 - 41 years
Patent Fallopian tubes, proven by hysterosalpingography (HSG), a negative Chlamydia

antibody titre (CAT) or diagnostic laparoscopy combined with tubal testing (DLS and TT), depending on the local protocol.
BMI < 40 kg/m2

Exclusion criteria

BMI > 40 kg/m2
Previous unsuccessful ovulation induction cycles with clomiphene citrate
Double-sided tubal pathology
Moderate - severe male infertility (TMSC < 3 million)
Grade III/IV endometriosis

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2016
Enrollment:	42
Type:	Actual

Ethics review

Approved WMO

Date:	29-04-2016
Application type:	First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL56254.091.15