

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Sexual function and fertility disorders
<b>Study type</b>	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**

### **Public**

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### **Scientific**

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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/m<sup>2</sup>

## Exclusion criteria

BMI > 40 kg/m<sup>2</sup>

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

## 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