

# Does endometrial scratching increase the rate of spontaneous conception in couples with unexplained infertility and a good prognosis (Hunault >30%)?

Published: 28-09-2017

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To assess whether endometrial scratching increases live birth rates in couples with unexplained infertility and a good prognosis (Hunault>30%)?

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Sexual function and fertility disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON52881

### Source

ToetsingOnline

### Brief title

SCRaTCH OFO trial

### Condition

- Sexual function and fertility disorders

### Synonym

Infertility / Subfertility

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** ZonMW Doelmatigheid

## Intervention

**Keyword:** Infertility, SCRaTCH, Spontaneous Pregnancy, Unexplained

## Outcome measures

### Primary outcome

Cumulative live birth rate (of which the \*ongoing\* status should be achieved within 12 months).

### Secondary outcome

- Live birth rate with ongoing pregnancy within 12 months after randomisation
- Live birth rate 3 months after randomization
- Ongoing pregnancy rate
- Clinical pregnancy rate
- Biochemical pregnancy rate
- Biochemical pregnancy loss rate
- Miscarriage rate
- Multiple pregnancy rate
- Time to pregnancy
- Progression to IUI treatment
- Progression to IVF treatment
- Costs
- Endometrial tissue (including endometrial gene expression analysis, endometrial microbiome analysis)

- Endometrial organoids
- Pregnancy complications
- Complications of endometrial scratching
- Vaginal swabs (vaginal microbiome analysis) (only in UMC Utrecht in women who are randomized for scratch)

## Study description

### Background summary

In up to 50% of subfertile couples infertility is diagnosed as being \*unexplained\*. Some of these couples may have an endometrial factor that negatively impacts implantation. It has been suggested that the chances of implantation after IVF are increased by intentionally injuring (\*scratching\*) the superficial lining of the womb. The inflammatory response will enable the endometrium to acquire a state of optimal receptivity thereby positively affecting live birth rates. Women with unexplained infertility in a strategy of expectant management may also benefit from this scratching procedure.

### Study objective

To assess whether endometrial scratching increases live birth rates in couples with unexplained infertility and a good prognosis (Hunault > 30%)?

### Study design

Randomized controlled non-blinded multi-center superiority trial with 12 months of follow-up. We will include 396 women in each arm (total 792) to identify a meaningful difference between the comparison groups

### Intervention

Endometrial scratch during the luteal phase: 6/7 days after the LH-surge. If patients do not want to undergo the scratch during the luteal phase, patients can indicate this and have the procedure scheduled during the follicular phase. The scratch will then be scheduled between cycle day 5 and 11; in case of a mean cycle duration of 25 days or shorter, the scratch is planned on cycle day X (cycle duration minus 15 days) at the latest.

## Study burden and risks

Patients who are randomized for endometrial scratching will pay one extra visit to the hospital. From existing literature it is clear that the rate and extent of adverse events is very low. The benefit is a potential increase in the chance to conceive.

## Contacts

### Public

Academisch Medisch Centrum

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CX 3584

NL

### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

### Inclusion criteria

1. Diagnosis of Unexplained Infertility (UEI) and a Hunault of > 30%.
2. Female age 18-38 years
3. Primary or secondary infertility lasting at least 1 year
4. Regular menstrual cycle

5. Patent tubes (diagnosed by negative Chlamydia antibody titre and absence of risk factors for tubal disease, and/or hysterosalpingography or diagnostic laparoscopy)
6. Total motile sperm count > 3 million
7. Normal transvaginal ultrasound, defined as no visible intracavitary pathology or intramural myomas with impression of the uterine cavity
8. Written informed consent

## Exclusion criteria

1. History of lower abdominal or pelvic infection
2. Previous surgical procedures of the uterine cervix or cavity
3. Endometriosis grade 3 and 4
4. Previous caesarean section with niche formation
5. The presence of untreated unilateral or bilateral hydrosalpinx
6. Recurrent miscarriage (defined as 2 or more pregnancy losses prior to 20 weeks of gestation)
7. Previous endometrial scratching
8. Meno-metrorrhagia (defined as any intermenstrual loss of blood)
9. Untreated/unsubstituted endocrine abnormalities (e.g. pituitary, thyroid, adrenal or pancreas)

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	17-11-2017
Enrollment:	792

Type:

Actual

## Ethics review

Approved WMO

Date: 28-09-2017

Application type: First submission

Review commission: METC NedMec

Approved WMO

Date: 16-11-2017

Application type: Amendment

Review commission: METC NedMec

Approved WMO

Date: 04-01-2018

Application type: Amendment

Review commission: METC NedMec

Approved WMO

Date: 24-02-2018

Application type: Amendment

Review commission: METC NedMec

Approved WMO

Date: 06-03-2018

Application type: Amendment

Review commission: METC NedMec

Approved WMO

Date: 24-04-2018

Application type: Amendment

Review commission: METC NedMec

Approved WMO

Date: 26-06-2018

Application type: Amendment

Review commission: METC NedMec

Approved WMO

Date: 10-07-2018

Application type: Amendment

Review commission: METC NedMec

Approved WMO	
Date:	14-08-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	22-08-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	05-09-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	11-09-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	17-10-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	30-10-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	20-11-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	09-01-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	23-01-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	24-04-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	22-05-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	11-09-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	11-12-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	08-01-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	15-04-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	01-05-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	16-06-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	15-07-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	



Date:	08-09-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	12-10-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	27-10-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	08-12-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	04-02-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	15-04-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	18-01-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	21-02-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	28-12-2022
Application type:	Amendment
Review commission:	METC NedMec

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 22066

Source: Nationaal Trial Register

Title:

### In other registers

Register	ID
CCMO	NL62675.041.17
Other	NTR Kandidaattrial 27811
OMON	NL-OMON22066