

# Management of unexplained infertility

<b>Submission date</b> 17/09/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/10/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/04/2016	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Cervical mucus is a thick gelatinous substance that is discharged at various times during a menstrual cycle of a woman. The nature of this mucus is key in indicating the fertility of the woman at that point and thereby the ease of getting pregnant. In this study, we want to find out if removing the cervical mucus before performing intrauterine insemination (to medically assist getting pregnant) improves pregnancy outcomes in patients with unexplained infertility.

### Who can participate?

Couples with unexplained infertility.

### What does the study involve?

Participants will be randomly allocated to one of two groups. In participants allocated to the first group, cervical mucus will be removed before the intrauterine insemination procedure. Women allocated to the second group will not have their cervical mucus removed. The rates of pregnancy will be compared to find out if this works well.

### What are the possible benefits and risks of participating?

Participants may benefit from an improved chance of pregnancy. There will not be any risks.

### Where is the study run from?

1. Menoufiya University Hospital (Egypt)
2. Al-Hayat National Hospital, Kingdom of Saudi Arabia (KSA)

### When is the study starting and how long is it expected to run for?

November 2014 to August 2016.

### Who is funding the study?

1. Menoufia University (Egypt)
2. Hayat National Hospital (Kingdom of Saudi Arabia)

### Who is the main contact?

Dr Mohamed Maher  
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# Contact information

## Type(s)

Scientific

## Contact name

Dr Mohammad Maher

## ORCID ID

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101

# Additional identifiers

## Protocol serial number

5

# Study information

## Scientific Title

Cervical mucus removal prior to intrauterine insemination: can it improve pregnancy rates in women with unexplained infertility?

## Study objectives

The aim of this study is to detect whether the removal of cervical mucus prior to IUI can improve pregnancy outcomes in subfertile patients with unexplained infertility.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Menoufia University ethical board (Egypt), 24/08/2014
2. Al-Hayat National Hospital ethical board (Saudi Arabia), 24/08/2014

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Cervical mucus removal

### **Interventions**

Patients will be randomized into two groups:

Group A: cervical mucus removal group

Group B: non-cervical mucus removal group, where only the external cervical os will be cleaned

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

Clinical pregnancy rate (defined as ultrasound evidence of pregnancy or products of conception identified by histopathological examination) per patient at 2 weeks following IUI

### **Key secondary outcome(s)**

N/A

### **Completion date**

01/03/2017

## **Eligibility**

### **Key inclusion criteria**

1. Women aged 35 years or less
2. Body mass index (BMI) 30 kg/m<sup>2</sup> or less
3. Diagnosis of unexplained infertility. The diagnosis of unexplained infertility was made according to the following points: normal semen analysis based on World Health Organization criteria (11), a preliminary transvaginal scan (TVS) on Day 2 of the cycle is normal with no detected ovarian pathology, normal (<10 IU/ml) follicular stimulating hormone (FSH) and luteinizing hormone (LH) measured on Day 2 of the cycle, normal serum prolactin level, normal thyroid function, midluteal serum progesterone levels >10 mg/dL, normal uterine cavity on hysterosalpingography or hysteroscopy, and patent tubes of normal appearance on hysterosalpingography and/or laparoscopy.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **Key exclusion criteria**

1. Women aged over 35
2. Hypogonadotropic hypogonadism
3. Diminished ovarian reserve (basal FSH level >10 IU/ ml)
4. Presence of resistant ovarian cyst (>20 mm for >1 month)

**Date of first enrolment**

29/10/2014

**Date of final enrolment**

01/12/2016

## Locations

**Countries of recruitment**

Egypt

Saudi Arabia

**Study participating centre**

**Menoufiya University Hospital**

Shebin Elkom

Egypt

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**Study participating centre**

**Al-Hayat National Hospital**

Umm Sarar

Khamis Mushait

Saudi Arabia

62461

## Sponsor information

**Organisation**

Menoufiya University Hospital (Egypt)

**ROR**

<https://ror.org/03sq8r703>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Menoufia University (Egypt)

**Funder Name**

Hayat National Hospital (Saudia Arabia)

## **Results and Publications**

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Other