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Management of unexplained infertility

Submission date	Recruitment status	[X] Prospectively registered
17/09/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/10/2014	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/04/2016	Pregnancy and Childbirth	[_] 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
mohamaher2015@gmail.com

Contact information

Type(s)
Scientific

Contact name
Dr Mohammad Maher

ORCID ID
http://orcid.org/0000-0002-7332-5215

Contact details
Khamis Mushyat
Khamis Mushyat
Saudi Arabia
101

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
N/A

Overall study start date
01/10/2014

Completion date
01/03/2017

Eligibility

Key inclusion criteria
1. Women aged 35 years or less
2. Body mass index (BMI) 30 kg/m2 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

Age group
Adult

Sex
Female

Target number of participants
At a study power of 80% with an á = 0.05, the total required cycles will be 714

Key exclusion criteria
1. Women aged over 35
2. Hypogonadotrophic 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
101

Study participating centre
Al-Hayat National Hospital
Umm Sarar
Khamis Mushait
Saudi Arabia
62461

Sponsor information

Organisation
Menoufiya University Hospital (Egypt)

Sponsor details
Shebin Elkom
Shebin Elkom
Egypt
101

Sponsor type
University/education

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

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other