Management of unexplained infertility

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 \dot{a} = 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