# Hydrotubation before intrauterine insemination in unexplained infertility

Submission date	Recruitment status	Prospectively registered
25/05/2009	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
03/07/2009	Completed	Results
Last Edited	Condition category	Individual participant data
03/07/2009	Urological and Genital Diseases	Record updated in last year

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

**Prof Mohamed Aboulghar** 

#### Contact details

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#### Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

# Study information

#### Scientific Title

Prospective randomised study for hydrotubation versus no hydrotubation before intrauterine insemination in unexplained infertility

#### **Study objectives**

Hydrotubation before intrauterine insemination (IUI) may improve pregnancy rate.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethical committee of the Egyptian IVF center approved on the 20th December 2008 (ref: 4/2009)

#### Study design

Prospective 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

Infertility

#### **Interventions**

Intervention: hydrotubation was performed on the day of randomisation and IUI was performed next day

Control: identical treatment to above apart from no hydrotubation

#### Intervention Type

Other

#### **Phase**

Not Applicable

#### Primary outcome measure

Ongoing pregnancy rate up to 20 weeks

#### Secondary outcome measures

- 1. Pain
- 2. Discomfort

Measured in the first week after hydrotubation.

#### Overall study start date

01/01/2009

#### Completion date

01/11/2009

# **Eligibility**

#### Key inclusion criteria

- 1. Females aged below 40 years
- 2. Diagnosis of unexplained infertility based on patent tubes diagnosed by hystersalpingography and/or laparoscopy
- 3. Regular cycles with ovulatory mid-luteal progesterone
- 4. Normal semen parameters of the husband according to World Health Organization (WHO) criteria
- 5. No previous treatment during the past 3 months

#### Participant type(s)

Patient

#### Age group

Adult

#### Sex

Female

#### Target number of participants

228

#### Key exclusion criteria

- 1. Tubal factor
- 2. Male factor
- 3. Ovulatory factor

#### Date of first enrolment

01/01/2009

#### Date of final enrolment

01/11/2009

### Locations

#### Countries of recruitment

Egypt

# Study participating centre 10 Geziret El Arab St.

Cairo Egypt 12411

# Sponsor information

#### Organisation

The Egyptian IVF-ET Center (Egypt)

#### Sponsor details

3, St 161 Hadaek El Maadi Cairo Egypt 12411 ivf@link.net

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.egyptianivfcenter.com/

#### **ROR**

https://ror.org/035aahr55

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

The Egyptian IVF-ET Center (Egypt)

## **Results and Publications**

#### Publication and dissemination plan

Not provided at time of registration

Intention to publish date

# Individual participant data (IPD) sharing plan

**IPD sharing plan summary**Not provided at time of registration