

# TRial of OutPatient HYsteroscopy in in-vitro fertilisation (IVF)

|                                        |                                                       |                                                                                                              |
|----------------------------------------|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>05/02/2009   | <b>Recruitment status</b><br>No longer recruiting     | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>06/02/2009 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>05/05/2016       | <b>Condition category</b><br>Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data                                                         |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Tarek El-Toukhy

**Contact details**  
Assisted Conception Unit  
11th Floor, Tower Wing  
Guy's Hospital  
Great Maze Pond  
London  
United Kingdom  
SE1 9RT  
+44 (0)20 7188 0497  
tarek.el-toukhy@gstt.nhs.uk

## Additional identifiers

**Protocol serial number**  
0102

## Study information

**Scientific Title**

A multicentre randomised controlled study of the effects of outpatient hysteroscopy on the outcome of the subsequent in-vitro fertilisation (IVF) cycle after recurrent IVF failure

**Acronym**

Trophy in IVF

**Study objectives**

A recent systematic review suggested the outcome of in-vitro fertilisation (IVF) treatment could be improved in patients who have experienced recurrent IVF failure if an outpatient hysteroscopy (OH) is performed prior to starting the new treatment cycle. The review recommended performing a randomised trial to settle this research question. Therefore, this trial proposes to test the hypothesis that performing an OH prior to starting an IVF cycle improves the live birth rate of the subsequent IVF cycle in women who have experienced 2 - 4 previous failed IVF cycles.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Primary study design**

Interventional

**Study design**

Randomised single-blind controlled trial

**Study type(s)**

Treatment

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

Recurrent in-vitro fertilisation (IVF) failure

**Interventions**

The trial participants are randomised to one of two regimens:

1. Out-patient hysteroscopy in the follicular phase (days 5 - 14) of the menstrual cycle where the IVF cycle is due to start, followed by standard IVF treatment (according to local standard IVF protocol with or without the use of intracytoplasmic sperm injection)
2. Standard IVF treatment (as above) without a prior out-patient hysteroscopy

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

Live birth event per cycle started, measured after 9 months of embryo transfer.

**Key secondary outcome(s)**

1. Embryo implantation rate
2. Pregnancy rate per IVF cycle started
3. Clinical pregnancy rate per IVF cycle started

4. Miscarriage rate per pregnancy achieved  
Measured 2 and 4 weeks after embryo transfer.

**Completion date**

30/06/2012

## Eligibility

**Key inclusion criteria**

1. Women undergoing an IVF (with or without intracytoplasmic sperm injection) treatment cycle who have had between 2 - 4 failed previous fresh IVF attempts ending in an embryo transfer
2. Aged 36 years or less
3. Willing and able to give informed consent

Women who have had a previous hysteroscopy will be included.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**Key exclusion criteria**

1. Women who had less than 2 or more than 4 failed fresh IVF attempts ending in an embryo transfer
2. Women aged more than 36 years (i.e. women aged 37 years or more)
3. Presence of submucous or intramural uterine fibroids distorting the uterine cavity or untreated tubal hydrosalpinges

**Date of first enrolment**

01/07/2009

**Date of final enrolment**

30/06/2012

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**  
Guy's Hospital  
London  
United Kingdom  
SE1 9RT

## Sponsor information

**Organisation**  
Guy's and St Thomas' NHS Foundation Trust (UK)

**ROR**  
<https://ror.org/00j161312>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
Guy's and St Thomas' NHS Foundation Trust (UK) - Assisted Conception Unit

## Results and Publications

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

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

### Study outputs

| Output type                      | Details  | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>  | results  | 25/06/2016   |            | Yes            | No              |
| <a href="#">Protocol article</a> | protocol | 03/12/2009   |            | Yes            | No              |