

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## 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

## **Study design**

Randomised single-blind controlled trial

## **Primary study design**

Interventional

## **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
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes