

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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?
Results article	results	25/06/2016		Yes	No
Protocol article	protocol	03/12/2009		Yes	No