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

Submission date	Recruitment status	[X] Prospectively registered
05/02/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/02/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Secondary outcome measures
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.

Overall study start date
01/07/2009

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

Age group
Adult

Sex
Female

Target number of participants
756

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
England

United Kingdom

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

Sponsor information

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

Sponsor details
Research and Development Department
Conybeare House
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Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/12/2009		Yes	No
Results article	results	25/06/2016		Yes	No