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Comparison of day 5 and day 6 embryo transfers for slow growing embryos for in vitro fertilisation (IVF) treatment

Submission date	Recruitment status	[X] Prospectively registered
27/11/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/12/2012	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
06/07/2018	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Literature confirms that fast developing blastocysts [blastocyst is a highly differentiated, highly developed embryo that has grown to the point where it is ready to attach to the uterine wall (implantation)] transferred on day 5 are associated with good pregnancy rates. The dilemma arises if there are no fast developing expanded blastocysts for transfer seen on day 5. What is the optimal time for transfer of these embryos? Would it be correct to transfer the best available less expanded embryos on day 5 or replace delayed blastocysts on day 6? There have been no studies to compare the implantation potential of slow developing day 5 blastocysts transferred on day 5 with those transferred on day 6. The aim of this study is to ascertain if differences exist in pregnancy outcomes in the two groups both with slow developing embryos on day 5: transfer of fresh day 5 slow developing embryos compared to transfer of day 6 fully developed blastocysts transferred on day 6.

Who can participate?
Women aged 21-45 undergoing in vitro fertilisation (IVF)/intra-cytoplasmic sperm injection (ICSI) treatment and reaching a day 5 embryo transfer but with no fast developing blastocysts on day 5 will be eligible to participate in the study.

What does the study involve?
Participants are randomly allocated into two groups. They either have an embryo transfer on day 5 or extended embryo culture and embryo transfer on day 6.

What are the possible benefits and risks of participating?
The participant may benefit from an improved pregnancy rate if allocated to a group which is later found to be superior to the other group. Embryo transfer is a part of routine treatment. The research protocol will only change the time of the embryo transfer. Hence there will be no additional risks or burdens of the research for the participant.

Where is the study run from?
The study will be carried out in a tertiary referral teaching university fertility unit

When is the study starting and how long is it expected to run for?
We aim to start the study by February 2013 and it is expected to last between 12-18 months

Who is funding the study?
Homerton University Hospital NHS Foundation Trust (UK)

Who is the main contact?
Dr Priya Bhide, Associate Specialist, Homerton University Hospital
priya.bhide@homerton.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Prof Roy Homburg

Contact details
Homerton Fertility Centre
Homerton Row
London
United Kingdom
E9 6SR

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FE1203

Study information

Scientific Title
When is the best time to replace slow developing embryos? A comparison between day 5 and day 6 transfers: a randomised controlled trial

Study objectives
Embryo implantation involves the complex interplay between the receptivity of the womb lining and embryo quality. The developmental potential of slower developing embryos is similar to faster developing ones as shown by similar outcomes for frozen embryos replaced in frozen embryo replacement cycles (Shapiro et al). However embryos with a faster developmental pace transferred on day 5 in a fresh cycle give an advantage in terms of clinical pregnancy rate over slower developing embryos transferred on day 6 (Shapiro et al). This suggests that delayed fresh transfers may have a suboptimal outcome due to embryo-endometrial asynchrony. The dilemma

arises if there are no fast developing embryos for transfer seen on day 5. There have been no randomised control trials which would point to the best timing for replacement of slow embryos in these women. Would it be correct to transfer the best available embryos on day 5, or replace embryos on day 6 after delayed culture?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pilot 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 contact Dr Priya Bhide (priya.bhide@homerton.nhs.uk) to request a patient information sheet

Health condition(s) or problem(s) studied
Subfertility patients undergoing IVF / ICSI treatment

Interventions
All participants will follow the routine IVF/ICSI protocol till the day of embryo transfer. Following this they will be allocated to either of the two study arms.

Study arm 1: patient to have embryo transfer on day 5
Study arm 2: patient to have extended embryo culture and transfer of embryos on day 6

Following embryo transfer all participants will again follow routine clinical care protocols standard to IVF.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Clinical pregnancy rate

Secondary outcome measures
Delayed blastocyst conversion rate

Overall study start date
01/02/2013

Completion date
01/02/2014

Eligibility

Key inclusion criteria
Women age 21-45 undergoing a single IVF / Intra-cytoplasmic sperm injection (ICSI) treatment with their own oocytes during the specified study duration who:
1. Proceed to have a day 5 transfer
2. Have no fast developing embryos for transfer on day 5

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
100

Key exclusion criteria
Women who have already participated in the study for a previous cycle

Date of first enrolment
01/02/2013

Date of final enrolment
01/02/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Homerton Fertility Centre
London
United Kingdom
E9 6SR

Sponsor information

Organisation
Homerton University Hospital NHS Foundation Trust (UK)

Sponsor details
Homerton Hospital
Homerton Row
London
England
United Kingdom
E9 6SR

Sponsor type
Hospital/treatment centre

Website
http://www.homerton.nhs.uk/

ROR
https://ror.org/01zpp3d44

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Homerton University Hospital NHS Foundation Trust (UK)

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