

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/12/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 06/07/2018	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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## Contact information

### Type(s)

Scientific

### Contact name

Prof Roy Homburg

### Contact details

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

Clinical pregnancy rate

**Key secondary outcome(s)**

Delayed blastocyst conversion rate

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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**

United Kingdom

England

**Study participating centre**

Homerton Fertility Centre

London

United Kingdom

E9 6SR

**Sponsor information****Organisation**

Homerton University Hospital NHS Foundation Trust (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****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration