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Cryopreservation of human embryos in a modified cryoprotectant solution

Submission date	Recruitment status	[ ] Prospectively registered
08/01/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/10/2014	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

Protocol serial number
067469

Study information

Scientific Title

Study objectives

The aim of the study is to improve the outcome of human embryo freezing. The immediate objective is to increase the proportion of embryos surviving cryopreservation with all blastomeres intact.

We hypothesise that an increase (from 0.1M to 0.3M) in the sucrose content of the freezing solution will increase the survival of slowly cooled cleavage stage human embryos. A greater proportion of cleavage stage embryos will survive with all cells intact and the increased survival will be reflected in the rate of implantation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Grampian Research Ethics Committee (GREC), 02/04/2003 (ref: 03/ 0067).

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
In Vitro Fertilisation (IVF) and Intra-Cytoplasmic Sperm Injection (ICSI)

Interventions
Freezing the embryos in a solution containing 0.3M sucrose.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Recovery of intact embryos after thawing: with 75 patients having embryos thawed in each arm, the study has a 90% power at 5% level of significance of detecting a 25% increase in the proportion of women with at least two intact embryos after thawing the whole cohort.

Since some patients may not return for thawing for several years we estimate that we need to freeze for at least 100 patients in each arm. We allowed two years to recruit and freeze, plus a further two years for sufficient thawing. We hope that a later follow up will also be possible.

Key secondary outcome(s)
1. Implantation rate
2. Miscarriage
3. Live birth

Sample size will not allow statement of significant differences.

Completion date
01/05/2008

Eligibility

Key inclusion criteria
1. In Vitro Fertilisation (IVF) and Intra-Cytoplasmic Sperm Injection (ICSI) patients - new patients and returning patients who were not previously approached for the trial
2. Patients using donor sperm if donor consented to research
3. Patients who consented but did not have sufficient embryos to enter the trial may be approached in a later cycle (re-consent needed)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Women in ECoSSE trial (see ISRCTN86466058 for details of this trial)
2. Women with two or more previous cycles but no freezing
3. Women 38 or over with one previous cycle but no freezing
4. Recipients of eggs

Date of first enrolment
01/05/2003

Date of final enrolment
01/05/2008

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre

Department of Obstetrics and Gynaecology
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Sponsor information

Organisation
University of Aberdeen (UK)

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (ref: 067469)

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	01/08/2011		Yes	No