

Cryopreservation of human embryos in a modified cryoprotectant solution

Submission date 08/01/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 01/02/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/10/2014	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

Contact name
Miss Catriona Aird

Contact details
Department of Obstetrics and Gynaecology
Maternity Hospital
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

1. Implantation rate
2. Miscarriage
3. Live birth

Sample size will not allow statement of significant differences.

Overall study start date

01/05/2003

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

Age group

Adult

Sex

Female

Target number of participants

200

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

Scotland

United Kingdom

Study participating centre

Department of Obstetrics and Gynaecology

Aberdeen

United Kingdom

AB25 2ZD

Sponsor information

Organisation

University of Aberdeen (UK)

Sponsor details

c/o Sylvia M Clement

Department of Obstetrics and Gynaecology

Foresterhill

Aberdeen

Scotland

United Kingdom

AB25 2ZD

Sponsor type

University/education

Website

<http://www.abdn.ac.uk/obsgynae>

ROR

<https://ror.org/016476m91>

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (ref: 067469)

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?
Results article	results	01/08/2011		Yes	No