

# Cryopreservation of human embryos in a modified cryoprotectant solution

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

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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).

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **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**  
Aberdeen  
United Kingdom  
AB25 2ZD

## 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?
<a href="#">Results article</a>	results	01/08/2011		Yes	No