# Comparison of the cryopreservation method for day 3 embryos using slow freezing or vitrification

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
19/11/2008	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
30/01/2009	Completed	Results
Last Edited	Condition category	Individual participant data
30/01/2009	Pregnancy and Childbirth	<ul><li>Record updated in last year</li></ul>

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

## Scientific Title

Randomised controlled trial comparing the implantation potential of a frozen-thawed cleavagestage embryo cryopreserved using vitrification or slow freezing

## **Study objectives**

To avoid multiple pregnancies, the proportion of elective single embryo transfers (SET) has increased substantially in our centre. Consequently, the impact of the cryopreservation program on the in vitro fertilisation (IVF)/intra-cytoplasmic sperm injection (ICSI) success rate is augmented since more surplus embryos become available. SET requires a cryopreservation program which optimally preserves the vitality of the surplus embryos. The first step to improve the efficiency of a cryopreservation program is to improve the post-thaw embryo survival. Retrospective analysis of our slow-cooling and thawing cryopreservation program showed that about 35% of day 3 cleavage stage embryos are severely damaged after freezing and thawing and are not suitable for transfer and another 15% is moderately damaged.

According to recent findings, vitrification as a new cryopreservation method is assumed to reduce cryo-damage and thus better preserves the embryo viability. During vitrification the formation of intracellular ice formation is prevented by short incubation of the embryos in high concentrations of cryoprotective agents. Successful vitrification of embryos at all preimplantation stages has been reported. Retrospective analyses show higher or similar survival and implantation rates after vitrification compared to the results obtained after traditional slow freezing and thawing. However, these data remain unvalidated in prospectively randomised studies.

The aim of the study is to compare the live birth rate after transfer of one frozen-thawed day 3 embryo using either vitrification or slow freezing as the cryopreservation method.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Medical Ethics Committee UZ Brussel-VUB gave approval on the 6th November 2008 (ref: B.U.N B14320084732)

# Study design

Double-blinded prospectively randomised 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 use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

In vitro fertilisation

## **Interventions**

IVF patients will receive a frozen-thawed embryo that was frozen using the vitrification method or the standard slow freezing method.

## Intervention Type

Other

#### **Phase**

Not Applicable

## Primary outcome measure

Live birth rate per frozen-thawed embryo

## Secondary outcome measures

- 1. Post-thaw survival of thawed embryos (the percentage of intact blastomeres on the total number of blastomeres present before freezing)
- 2. Post-thaw development of embryos after overnight culture
- 3. Implantation rate per transferred embryo
- 4. Ongoing pregnancy rate per thawing cycle
- 5. Live birth rate per transferred embryo

# Overall study start date

01/12/2008

# Completion date

01/12/2010

# **Eligibility**

## Key inclusion criteria

- 1. Female aged less than 38 years
- 2. Patients with day 3 single or double embryo transfer and surplus embryos frozen
- 3. Cryopreservation criteria:
- 3.1. 6 7 cell embryos on day 3 with less than or equal to 20% fragmentation
- 3.2. Greater than or equal to 8 cell embryos on day 3 with less than or equal to 50% fragmentation
- 3.3. No multi-nucleated embryos

## Participant type(s)

Patient

## Age group

Adult

## Sex

Female

# Target number of participants

306

## Key exclusion criteria

Patients with preimplantation genetic diagnosis treatment

## Date of first enrolment

01/12/2008

## Date of final enrolment

01/12/2010

# Locations

# Countries of recruitment

Belgium

# Study participating centre

**UZBrussel** 

Brussels Belgium 1090

# Sponsor information

# Organisation

Research Foundation Flanders (Belgium)

## Sponsor details

Egmontstraat 5 Brussels Belgium B-1000

## Sponsor type

Research organisation

## Website

http://www.fwo.be

## **ROR**

https://ror.org/03qtxy027

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

University Hospital Brussels (Universitair Ziekenhuis Brussel [UZ Brussel]) (Belgium) - covering incidental costs

# **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