

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Randomised controlled trial comparing the implantation potential of a frozen-thawed cleavage-stage 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

Study type(s)

Treatment

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(s)

Live birth rate per frozen-thawed embryo

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration