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

Submission date	Recruitment status	[ ] Prospectively registered
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	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

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