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Comparison of the efficacy of EasySperm® vitrification protocol vs conventional slow freezing in assisted reproduction treatments

Submission date
26/01/2018

Recruitment status
No longer recruiting

Registration date
01/02/2018

Overall study status
Completed

Last Edited
21/02/2023

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cryopreservation is the use of very low temperatures to preserve living cells and tissues. Sperm cryopreservation is an essential procedure of Assisted Reproduction Technologies (ART) to preserve male fertility and ensure that the specimen is available on the day of the egg retrieval regardless of the availability of the male partner. Currently, the most commonly used technique for sperm cryopreservation is slow freezing. Nevertheless, this technique has been shown to decrease sperm quality. During the last years, vitrification has been proposed as an alternative to conventional freezing. This technique is based on the ultra-rapid descent and rise of temperatures, avoiding ice crystal formation and its associated effects. Vitrification improves cell survival rates and reduces cell damage. This technique has been widely used for eggs and embryos but it has been hardly applied to human sperm. Recently, the development of EasySperm®, a new cryoprotectant-free vitrification method for human sperm, provided an improved and reliable alternative for sperm cryopreservation. This new method has been tested in normal sperm samples with better preservation of sperm quality compared to slow freezing. The aim of this study is to compare the effectiveness of the EasySperm® vitrification protocol with conventional slow freezing in ART cycles.

Who can participate?
Couples who are interested in ART with an egg donation program. The male patients should have normal sperm and be aged less than 45. The female patients should have no endometrial (womb lining) alterations and be aged less than 48.

What does the study involve?
Patients are randomly allocated to one of two groups: group 1: vitrification and group 2: slow freezing. In both groups sperm cryopreservation is performed using both the vitrification and slow freezing techniques. Half of the donated eggs are fertilised with vitrified/warmed sperm and the other half with frozen/thawed sperm. All embryos are grown to day 5 and single good quality embryos are transferred to the woman's womb. In group 1 the embryo is selected from the embryos produced by the vitrified/warmed sperm. In group 2 the embryo is selected from the embryos produced by the frozen/thawed sperm. Sperm fertilisation ability, embryo quality

and developmental potential and clinical outcomes are assessed and compared between the groups.

What are the possible benefits and risks of participating?
The results will show which technique is the best to be used in daily practice. The cryopreservation protocol based on vitrification is expected to result in better embryo development and quality and improved clinical outcomes. There are no risks of participating.

Where is the study run from?
1. IVF Spain Alicante (Alicante, Spain)
2. IVF Donostia (San Sebastian, Spain)

When is the study starting and how long is it expected to run for?
May 2016 to April 2021

Who is funding the study?
IVF Spain Foundation (Spain)

Who is the main contact?
Ms Llanos Medrano López-Tello

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2016ACE

Study information

Scientific Title
Comparison of the efficacy of EasySperm® vitrification protocol vs conventional slow freezing in assisted reproduction treatments

Acronym
CEES

Study objectives
The cryopreservation protocol based on vitrification is expected to result in better embryo development and quality and improved clinical outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Alacant General Hospital, 01/07/2016, ref: CEIC PI2016/18

Study design

Prospective 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Human fertility

Interventions
The method of randomisation: the history number of the patients is used for the randomisation: odd number goes to group 1, even number to group 2.

Group 1: Sperm cryopreservation will be performed using both vitrification and slow freezing techniques. Half of the donated oocytes will be fertilised with vitrified spermatozoa and the other half with frozen spermatozoa. The best single good morphological quality blastocyst (BB quality at least) among the embryos produced by vitrified/warmed spermatozoa will be selected and transferred.

Group 2: Sperm cryopreservation will be performed using both vitrification and slow freezing techniques. Half of the donated oocytes will be fertilised with vitrified spermatozoa and the other half with frozen spermatozoa. The best single good morphological quality blastocyst (BB quality at least) among the embryos produced by frozen/thawed spermatozoa will be selected and transferred.

Sperm fertilisation ability, embryo quality and developmental potential and clinical outcomes will be assessed and compared between the groups. The duration of follow-up is around 4 years.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pregnancy rates, measured using the hormone β-HCG for the positive beta, echography for the presence of sac, cardiac activity, all measured at one time (10 days after embryo transfer for the beta, in the 4th or 5th week after embryo transfer and 7th-9th week after embryo transfer, respectively). The results of the birth are obtained 10 months after embryo transfer.

Secondary outcome measures

1. Sperm quality parameters (sperm count, motility, morphology, vitality, apoptosis and DNA integrity measured by flow cytometry), measured on the day of egg retrieval (post cryopreservation)
2. Sperm competence in terms of fertilization rate and blastocyst formation rate. The fertilization rate is the number of zygotes with good fertilization vs number of eggs, recorded the day after egg retrieval (day 1 of development). The blastocyst formation rate is the number of blastocyst vs zygotes, recorded on day 5 and 6 of development.
3. Embryo quality measured using Gardner's cataloging (Gardner DK, Schoolcraft WB, 2008) and the kinetics of the embryos measured using an incubator with time-lapse technology. The embryo quality is assessed on day 5 and 6 (once a day) and the time-lapse data are collected on day 5 of development (once a day)
4. Chromosome status evaluated by PGD-A (Preimplantation Genetic Diagnosis for aneuploidy) and the results are obtained 20 days after egg retrieval

Overall study start date
01/05/2016

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. Couples who are interested in ART with an egg donation program
2. The male patients have to present a normozoospermic spermiogram and an age less than 45
3. The female patients have not to present endometrial alterations and an age less to 48

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 100

Total final enrolment
83

Key exclusion criteria
1. Couples who are interested in ART with own eggs
2. Male patients with not normozoospermic spermiogram and an age greater than 45
3. Female patients with endometrial alterations and more than 48 years old

Date of first enrolment
13/07/2016

Date of final enrolment
31/08/2019

Locations

Countries of recruitment
Spain

Study participating centre
IVF Spain
Av. Ansaldo
Alicante
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Sponsor information

Organisation
iGLS

Sponsor details
Carrer Britania
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Sponsor type
Other

Website
https://www.igls.net/es/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
IVF Spain Alicante

Results and Publications

Publication and dissemination plan
Academic outputs will include a minimum of two papers submitted to high-impact peer reviewed journals, and at least three conference presentations or workshops.

Intention to publish date
21/02/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Ms Llanos Medrano López-Tello once the process is finished, estimated to be in 1 year.

IPD sharing plan summary
Available on request