E-Freeze

Couples Information Leaflet

NHS
National Institute for Health Research

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You are due to undergo in vitro fertilisation (IVF) or intra-cytoplasmic sperm injection (ICSI) treatment where embryos are created in the laboratory before being replaced within the uterus. We would like to tell you about a research study that is taking place at this centre, which we would like to invite you to participate in.

What is the purpose of this research study?

The main aim of this research study is to find out which method of embryo transfer results in a higher healthy baby rate. One in seven couples experience difficulty in conceiving and many of them will require in vitro fertilisation (IVF). IVF involves hormone injections to stimulate a woman's ovaries to produce eggs which are then removed by a minor operation and mixed with sperm to create embryos in the laboratory. Usually these embryos are replaced within the uterus in 3 to 5 days. This is called fresh embryo transfer. Any remaining embryos are usually frozen so that they can be thawed and transferred at a later date if required - a process known as thawed frozen embryo transfer. Both forms of embryo transfer are commonly used as part of routine IVF treatment.

There have been some small studies, which suggest that using thawed frozen embryos may lead to improved pregnancy rates. This is because when frozen embryos are used, there is a delay in embryo transfer, allowing the excess hormones of ovarian stimulation to wear off, giving the uterus time to return to its natural state.

However, as only a few, small studies have currently been done, we do not know which procedure is better for IVF treatment and without further research we cannot say whether fresh or frozen thawed embryo transfer leads to a higher number of healthy babies born. The E-Freeze study will compare these two procedures of embryo transfer in 1,086 couples from IVF centres throughout the UK over the next 2 years to find out which one will give the best chance of having a healthy baby or whether there is no difference at all. Whilst there may be no benefit to being in either treatment arm (fresh or frozen thawed embryo transfer) any risk or adverse effects are unlikely.

This research study will help provide information on the best way of delivering IVF treatment in the future in terms of effectiveness, safety and cost, to both yourselves and the health service.

Why have I been invited to take part?

You are being asked to take part in this research study because the fertility centre has recommended that you are about to undergo IVF/ICSI treatment.

Do I have to take part?

No. It is entirely your decision whether or not to take part in the research study. If you decide not to, your care will not be affected in any way. If you decide you would like to take part, you can change your mind at any time up to the day of embryo freezing. You can withdraw from the study without having to give a reason.

What will happen if I do take part?

If you agree to take part, you and your partner will be asked to sign a consent form. We will collect clinical information about you both, including any previous pregnancies and fertility treatment from your notes. Your scheduled IVF/ICSI treatment will proceed as planned. You will receive hormone injections to help the ovaries produce mature eggs, regular ultrasound scans and blood tests to monitor your ovaries. A surgical procedure will be done to collect eggs. These eggs will be mixed (IVF) or injected (ICSI) with sperm to create embryos in the laboratory. If you have three good quality embryos 3 days after egg collection you will be randomly allocated to receive either fresh or frozen embryo transfer. The random allocation to the treatment arms is just like 'tossing a coin' and you will have a 50:50 chance of being placed in either of two treatment groups:

- The fresh embryo transfer group – where you will have a fresh embryo transfer within a week of egg collection and creating embryos, and any remaining good quality embryos will be available to be frozen.

- The thawed frozen embryo transfer group – where all good quality embryos will be frozen, to be thawed and transferred at a later date. Embryo transfer typically takes place 4 to 6 weeks later and always within 3 months of egg collection. Your clinic/ research nurse will discuss the date of your embryo transfer with you. This is the time that it takes for the effects of hormone injections to wear off. There will be a few visits to hospital to prepare the lining of the womb.

Neither you, nor your doctors can decide which treatment you will receive. The fertility centre will telephone you on day 3 to let you know to which group you have been assigned and make the necessary arrangements.

You will also be asked to fill in a very short questionnaire about how you are feeling at the time of consent. At embryo transfer you will be asked to complete this questionnaire again, plus a questionnaire asking about time taken and any additional expenses incurred attending the clinic.

Two weeks after embryo transfer your clinic will arrange a pregnancy test. If this is positive, an ultrasound scan will be arranged 3 weeks later to visualise the pregnancy. If all is well, you will be referred for antenatal care in the usual way.

Everyone in the study will be followed up in exactly the same way until 2 weeks after embryo transfer. If your treatment results in a pregnancy, we will be in touch during and after the end of the pregnancy to collect information about your health and that of your baby. A research nurse from your clinic will contact you by telephone at various time points (12 weeks, and 28 weeks and approximately 6 weeks after delivery).

In the event that your IVF treatment does not result in 3 good quality embryos, you will not be included in this study. Instead, you will be offered the most appropriate standard treatment by the fertility centre.

What are the possible risks and benefits of taking part?

We do not expect any harm to come to you by taking part in this research study. All the procedures involve standard techniques which are already being used by IVF clinics. Your participation in this study should not involve any additional risk to you or your children.

If you are randomised to delayed embryo transfer, there will be no additional charge for freezing embryos and first thawed embryo transfer.

Replacement of frozen thawed embryos is an integral part of standard care in IVF. All the centres taking part in this research have excellent success rates with frozen embryo transfer. While not all embryos which are frozen survive the freezing and thawing process, the chance of this happening in couples with three good quality embryos on day 3 is negligible. To date, studies on many thousands of children born from embryo freezing have not shown any cause for concern.

It is unlikely that any information generated by this study will change the care you receive. However we hope that this research will improve the success of IVF/ICSI treatment for couples in the future.

Will taking part in this study be kept confidential?

If you take part in the study, some personal information such as your name, address and other contact details will be collected. These details will be held securely by the study managers in Oxford and will only be used by members of the research team to contact you. The Health and Social Care Information Centre and other central UK NHS bodies may be used to help contact you or provide information about your health status.

Information will be held on a secure online database designed specifically for this trial and will only be accessible by those involved in the research. Non-identifiable data from this study may be shared with other researchers who are doing similar work. To make sure that the study is being carried out correctly, your health records may be looked at by representatives of the research study sponsors (University of Aberdeen and NHS Grampian), research study organisers and your local NHS Trust.

What if relevant new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, any new information that is likely to affect your participation in the study in any way will be discussed with you. You will be free to decide whether to continue with the study. If you decide to withdraw, your care will not be affected. If the study is stopped for any reason, we will tell you and let you know what will happen next.

What will happen if I don't want to continue with the research study?

You can withdraw from the study at any time. We will ask you if we may use the data collected up to the point of your withdrawal in the analysis of the study.

What if there is a problem?

If you have a concern about any aspect of this study you should ask to speak to the doctor or nurse who is leading the study at your hospital (their contact details can be found at the end of this information sheet). You can also talk to the Patient Advice and Liaison Service – contact details can be obtained from your local hospital. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints mechanisms (or similar pathway in a private institution).

In the unlikely event that something goes wrong, you may have grounds for legal action and could seek compensation through the research sponsors of the study, University of Aberdeen and NHS Grampian although you may have to pay for your legal costs. Contact details for research sponsors are available through the research team. If you were in any way harmed and it is due to any routine clinical treatment or negligence then for those centres where NHS centres are providing the clinical treatment NHS indemnity arrangements will apply.

Involvement of your General Practitioner (GP)

With your permission, your GP will be informed of your participation in the study and they will receive a copy of this information leaflet for their records.

What will happen to the results of the research study?

At the end of the research study, the results will be analysed and published in medical journals. We will send you a summary of the final results of the study. A copy of the full journal article can be requested from the National Perinatal Epidemiology Unit (NPEU) in Oxford. You will not be identified in any report or publication about the study.

Who is organising and funding the research?

The research study is the responsibility of the University of Aberdeen but is run by the National Perinatal Epidemiology Unit, Clinical Trials Unit which is a department of Oxford University. It is funded by the Health Technology Assessment programme within the National Institute for Health Research [http://www.hta.ac.uk].

Who has reviewed the research study?

All research involving NHS patients has been approved by an NHS Research Ethics Committee before it goes ahead. Approval means that the Committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits, and that you have been given sufficient information on which to make an informed decision whether to take part or not. The North of Scotland Research Ethics Committee has reviewed and approved this study.

Local E-Freeze contacts

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