A trial of egg recovery rates for IVF using a collection chamber that provides environmental control: Eggcell Trial.

Stage 1

Participant Information Sheet

Version 3.0, 28/11/2018

Invitation

You are being invited to take part in a research study. Please read the following information to help you decide if you want to take part. We would like you to understand why we are doing this research and what it means for you. You do not need to make a decision straight away, so please feel free to talk to others about the study if you wish. Please ask us if there is anything that is not clear or if you want to know more.

Please remember that you do not have to take part and your normal healthcare will not be affected in any way, whatever you decide.

Part 1

What is the purpose of this study?

We have developed a new device (Eggcell) into which the eggs are collected during the egg collection procedure. Currently the fluid that is taken from the ovary goes into a test tube and is there exposed to the air. The new device is an airtight container that is filled with an approved egg culture medium so that the eggs never come in contact with the air. We have shown that this provides a more stable and protected environment.
The purpose of this first study is to use Eggcell in a small number of women having IVF so that we can confirm that it works in the clinic. If successful, we plan a much larger study to find out if the IVF outcome improves.

What would taking part involve?

Initially we will look at your fertility clinic notes to find out if you are eligible to take part. This will not involve any additional tests. This purpose of this is to make sure that you are suitable for participation in the study. If you are not suitable, this would usually be because you are not likely to grow many eggs and we would then prefer to offer you the standard egg collection method. We will explain the reasons to you.

If suitable, we would ask if you would be willing to let us collect your eggs using the Eggcell method. From your perspective, the egg collection procedure would be the same as the usual method of egg collection were used. It is the container that the eggs are collected into that is different.

We would also like to collect information from your fertility clinic notes about your treatment and its outcome. If you are happy to participate in this research, you will need to sign a consent form.

What are the possible benefits of taking part?

We know that Eggcell provides a more stable environment for the eggs and are hopeful that it will improve their quality. However, we do not yet know if it will improve the outcome of treatment. Therefore, there is no evidence at present that there will be any benefit to you from participation in the study.

What are the possible risks of taking part?

Our initial study in research volunteers indicated that the number of eggs collected was not reduced or damaged. The results also provided encouraging fertilization and embryo development rates but the number of subjects was small so we are still cautious. This will be the first time that we have used Eggcell for IVF patients so there remains a very small risk that the chance of pregnancy will be reduced.

To minimise the risk that participating in the study will affect your chance of pregnancy, we will only include you in the study if you grow 10-20 mature follicles before the egg collection.

What will happen to me if I take part?

A member of the research team will talk to you about the trial and answer any questions that you have. You will be asked to sign the Consent Form.
When you have your final scan we will count the number of follicles in your ovary. If you have 10-20 follicles you will be eligible to participate in the study. If you do not grow this number of follicles, your treatment may continue as routine and no further data about you will be collected.

If we use Eggcell, we would also like to collect information from your fertility clinic notes about your medical and fertility history and to record the outcome of your fertility treatment.

Will participating in research affect our treatment?

Apart from the egg collection method, your treatment will not be affected by the study both before and after the egg collection. The method of fertilising the egg and looking after any embryos will be as normal.

What will happen if I don't want to carry on with the study?

You may withdraw from the study at any time without giving a reason. If you decide to withdraw after the procedure we would not collect any further information about you from

your fertility clinic notes. However, we would like to use the information previously provided. If you decide that you don't want this information used in the study please contact a member of the study team so it can be removed.

Will I be paid for taking part?

There will be no need for any further visits or procedures that increases the cost of treatment. However, since this is a novel procedure in IVF, the outcome is unknown. Consequently, you will receive £1,500 compensation if we use Eggcell to collect your eggs. Please note that this will be taxable and could affect benefits.

Part 2

Will my GP be told about my involvement in this study?

If you decide to take part in this study and consent to have your GP informed then we will inform your GP. Your participation in the study will also be noted in your medical records.

Will my taking part in research be kept confidential?

The Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH) is the sponsor for this study. They will be using information from you and your fertility clinic notes in order to undertake this study and will act as the data controller (legally responsible for data security) for this study. This means that they are responsible for looking after your information and using it properly.

Your data will be held securely according to HFEA and NHS Trust regulations and will only be available to those on the HFEA license at the centre you are attending. Under UK Data protection laws, the Data Custodians (managers of access to the data) are the study Chief Investigator (Prof Alison Murdoch) and the Head of Department at the centre you are attending (insert name)

Data collected from you and your fertility clinic notes during the study will be looked at by people directly involved in the study, as well as by people who are monitoring and auditing the study who are approved by the HFEA. This is to make sure the study is being run correctly. This may include staff from the Newcastle Clinical Trials Unit, the Human Fertilisation and Embryology Authority (HFEA), the Medicines and Healthcare products Regulatory Agency (MHRA), the study Sponsor or the NHS department who manage research in the Trust. All will have a duty of confidentiality to you.

To safeguard your rights, we will use the minimum amount of personally-identifiable information possible. Your date of birth and initials will be held securely in the study database The people analysing information gathered in this study eg statisticians will not be able to

identify you. All personal details will be kept confidential and all identifying information about your treatment including information about participation in the study, will be held at (insert centre name). Under NHS regulations, you have the right of access to the medical data about you that is held in the centre you are attending.

According to HFEA regulations, all data about your treatment including information about your participation in research will be stored for 30 years.

You can find out more about how your information is used at
https://www.hra.nhs.uk/information-about-patients/

What will happen to the results of the research study?

Whenever possible we will publish the results of our studies in scientific journals. We also plan to present data at scientific conferences. You will not be named in any publication or presentation of the study results. We would also like to send you a newsletter with a summary of our results. Please let the research team know if you want to receive the newsletter.

Who is organising and funding the research?

This study is funded by a National Institute for Health Research (NIHR) i4i Development Award. The study is sponsored and indemnified by the Newcastle Upon Tyne NHS Foundation Trust and Newcastle University. The Newcastle Clinical Trials Unit is managing the study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a NHS Research Ethics Committee (REC). This is to protect your interests. This study has been reviewed and given a favourable opinion by Newcastle and North Tyneside Research Ethics Committee 2 and been approved by the NHS Health Research Authority (HRA). The study has also been given a notice of no objection by the Medicines and Healthcare products Regulatory Agency (MHRA).

Research in the fertility field is regulated by the Human Fertilisation and Embryology Authority (HFEA). Information about this organisation can be found on www.HFEA.gov.uk. This work is covered under the HFEA Treatment License 0017.

What if relevant new information becomes available?

The study team will ensure the patients are receiving the most appropriate and up to date medical care they require.

What if something goes wrong?

If you have a concern about any aspect of the study please contact your local team (see contact details below). Alternatively you can contact one of the researchers running this study, Nilendran Prathalingam (0191 2138213) and Professor Alison Murdoch (0191 213 8213) to discuss your concerns.

Your local contact people for the study are:

Contact Details of local PI:	Contact details of local Research Nurse:
Name:	Name:
Address:	Address:
Phone:	Phone:
Email:	Email:

If you are still unhappy and wish to complain formally and confidentially you can do this through the NHS complaints procedure by speaking to a member of the PALS (Patient Advise and Liaison Service) on 0800 0320 202 or by visiting www.PALS.nhs.uk.

In the event that something goes wrong and you are harmed during the research due to someone's negligence, then you may have grounds for a legal action for compensation against Newcastle upon Tyne Hospitals NHS Foundation Trust but you may have to pay your legal costs.

How have patients and the public been involved in this study?

We carried out interviews with five individuals who were undertaking IVF treatment at the Newcastle clinic to understand their views about the IVF process and their embryos.
We have set up patient focus groups made up of patients that are not participating in the study. Both male and female partners were recruited. These groups have helped to design the study and study documents.

The group will meet when the trial is near completion to have input into the interpretation of the results. Their views of Eggcell on egg and embryo quality will be evaluated. This will inform the publication of results. Patient views about the dissemination of results and ethical marketing of Eggcell will be discussed.

Thank you for taking time to read this information sheet