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

Submission date
15/12/2016

Recruitment status
Suspended

Registration date
27/02/2017

Overall study status
Suspended

Last Edited
15/12/2022

Condition category
Pregnancy and Childbirth

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

Plain English Summary

Background and study aims
About 1 in 7 couples have difficulty conceiving and infertility is recognised to be one of the most life-changing events in healthy young adults. In most cases, IVF is the only option that will improve their chance of a family. Routine IVF treatment involves collecting eggs by inserting a needle through the vagina into the follicles in the ovary. Each follicle contains an egg. The eggs are then taken to the laboratory to be mixed with sperm to create an embryo. The embryo is then transferred to the womb about 3-5 days later. During this procedure eggs and embryos are outside the protective environment of the body and are susceptible to environmental stress. There is a lot of evidence to show that the stage of development of eggs at this time is extremely sensitive to temperature and pH (acidity) changes and that controlled temperature and pH are necessary for successful fertilization. “Eggcell” is a medical device which has been developed to allow collection of eggs into an enclosed, warm environment. This protects the eggs from the environmental variations that occur in the standard test tube procedures. Eggcell use may improve the chance of eggs developing normally. The aim of this study is to compare egg recovery rates using Eggcell compared to standard techniques.

Who can participate?
Women aged 23-39 who are undergoing routine IVF treatment.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have their eggs collected using the standard test tube method. Those in the second group have their eggs collected using the Eggcell method. The clinical procedure for the patient is unchanged. The egg collection procedure will be explained to the patient (orally and in writing) prior to starting treatment according to routine clinical practice in both groups. Information is collected from the patients’ medical notes about medical and fertility history and to record the outcome of the fertility treatment. There are no follow up visits or assessments required and information about how many participants in each group become pregnant and have a baby is assessed by reviewing medical records.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
Newcastle Fertility Centre (UK)

When is the study starting and how long is it expected to run for?
February 2019 to November 2020 (updated 16/10/2020, previously: December 2020)

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Karen Nicholson
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
32163, Eudamed Number: CIV-GB-17-10-021745

Study information

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

Acronym
Eggcell

Study hypothesis
The aim of this study is to compare the recovery rate of eggs aspirated from the ovary using Eggcell (a medical device that enables collection of the fluid into an enclosed, warm environment) with the current test tube method.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/10/2016, North East - Newcastle & North Tyneside 2 Research Ethics Committee, ref: 16.NE.0330

Study design

Randomised; Interventional; Design type: Process of Care, Device

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Condition
Specialty: Reproductive health and childbirth, Primary sub-specialty: Reproductive and Sexual Medicine; UKCRC code/ Disease: Reproductive Health and Childbirth/ Other obstetric conditions, not elsewhere classified

Interventions
Participants will be randomised in the ratio 1:1 to receive either Eggcell or standard treatment using permuted random blocks of variable length. Randomisation will be stratified by site. An individual not otherwise involved with the study will produce the final randomisation schedule for use by this system.

Control group: Participants undergo egg collection using standard techniques. This involves a standard practice of ultrasound guided transvaginal egg collection carried out across the UK.

Intervention group: Participants undergo egg collection using the Eggcell procedure. The clinical procedure for the patient is unchanged for the routine planned procedure. The egg collection procedure will have been explained to the patient (orally and in writing) prior to starting treatment according to routine clinical practice. She will have signed the required treatment and HFEA consent forms.
Preparation for the clinical procedure will be carried out according to the clinic policy for ultrasound guided transvaginal egg collection. When the patient is positioned for egg collection, the “Flush’ foot pedal is depressed to pass warm fluid through the collection needle. This will ensure that the needle is warm before the procedure starts.
After insertion of the needle into the ovarian follicle, the ‘Collection’ foot pedal is depressed to aspirate the follicular fluid. When the follicle is fully collapsed according to the ultrasound appearance, the next follicle is treated. The egg collection procedure is completed according to routine practice.

There will be no follow up visits or assessments required from the patient that are related to participation in the Trial. For the collection of follow up data required for the Trial, this will be obtained by a review of their clinical records.

Intervention Type
Other

Primary outcome measure
Egg recovery rate per patient defined as the number of eggs recovered divided by the number of follicles aspirated is assessed on the egg collection day.

Secondary outcome measures
1. Fertilisation rate defined as the total number of fertilised eggs with 2PN seen on day 1divided by the total number of MII eggs retrieved on the egg collection day (day 1)
2. The number of TOP grade embryos on days 3 (cleavage stage) and 5 (blastocyst). Embryo development will be graded according to the United Kingdom National External Quality Assessment Service (UK NEQAS) grading system - Embryo Morphology Scheme .
3. Early treatment outcome defined as the presence of an intrauterine sac containing at least one foetal pulse per egg collection on day 14/+21 days
4. Implantation rate defined as the total number of foetal pulsations divided by the total number of embryos transferred on day 14/+21 days
5. Live birth rate defined as the total number of babies born divided by the total number of egg collections at 9 months/+3 months
6. Delivery rate per embryo defined as the total number live birth events divided by the total number of embryos transferred at 9 months/+3 months
7. Clinician’s experience of each procedure recorded using a questionnaire designed for the purpose of this study on the egg collection day
8. Embryologist’s experience of each procedure recorded using a questionnaire designed for the purpose of this study on the egg collection day

Overall study start date
29/04/2016

Overall study end date
30/11/2020

Eligibility

Participant inclusion criteria
1. Women having routine IVF treatment can be considered who have grown ≥10 and ≤20 follicles of size >/= 16mm in diameter as seen on the scan prior to hCG injection.
2. Provision of informed consent
3. Aged 23-39 (inclusive)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 749; UK Sample Size: 749

Participant exclusion criteria

1. Women who have grown less than 10 or more than 20 follicles of size 16mm in diameter
2. Unable to give informed consent
3. Insufficient English to allow completion of informed consent and study questionnaire
4. Women with a previous poor recovery rate (<50%)
5. Previous participation in this study
6. Women who have indicated that they do not wish to be involved in research

Recruitment start date
01/02/2019

Recruitment end date
19/10/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle Fertility Centre
Biomedicine West Wing
International Centre for Life
Times Square
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NE1 4EP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://newcastlejro.com/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Progress and final outcomes will be disseminated at relevant conferences by platform and poster presentations
2. The findings will be submitted for publication in peer reviewed journals. Results will also be reported to the Sponsor and Funder, and will be available on their websites. Manuscripts, abstracts and other modes of presentation will be reviewed by the Trial Steering Committee and Funder prior to submission. Individual patients will not be identifiable in any study report.
3. Planned feedback to centres via newsletters, trial close down meetings and publications. Feedback in the form of a lay summary will be provided to participants via a participant-specific

newsletter at the end of trial (if they indicated they wished to receive it) and by wider publicity generated.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to the strict confidentiality regulations of the HFEA and that specific combinations of clinical data could identify individuals.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2	05/01/2017	27/02/2017	No	Yes
Participant information sheet	version V3.0	28/10/2018	02/03/2020	No	Yes
Other publications	Eggcell laboratory validation prior to use with human participants	15/12/2022	15/12/2022	Yes	No