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Sharing of eggs produced during the IVF process for scientific research into fertility treatments, miscarriage, and the origin of genetic disorders

Submission date
08/02/2021

Recruitment status
Recruiting

Registration date
11/02/2021

Overall study status
Ongoing

Last Edited
06/10/2025

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
This research programme aims to understand molecular events at the beginning of human life. The study team perform basic scientific research that will underpin future improvements to fertility treatments and explain what happens when problems arise, such as genetic abnormalities. To date, they have relied solely upon studying eggs and embryos of insufficient quality for patient treatment, that would otherwise be discarded. Therefore, their results are sometimes challenged as lacking relevance to the ‘normal’ situation.

This study aims to open up a new source of 'high quality', potentially normal human eggs for research use. This study will provide important preliminary evidence about whether 'high quality' eggs differ from the current source and will test the feasibility of the study team's procedures.

This new arrangement benefits the research in two ways: first, providing ‘gold standard’ control eggs, most likely to be ‘normal’, against which to compare results with eggs derived from other sources. Second, it demonstrates the ability to source good quality eggs from young women. The study team are currently engaged in other funding applications and research plans. Having a source of 'high quality' research eggs strengthens applications and demonstrates capacity as well as increasing the robustness of the research conducted.

Who can participate?
Women aged 18 to 32 years who are planning IVF treatment at the Centre for Reproductive Medicine, Coventry.

What does the study involve?
During IVF treatment, women receive hormone treatment to stimulate the ovaries to produce many eggs at once. Women participating in this study will voluntarily provide half of their

collected eggs for use in research while keeping half for their own IVF treatment cycles. Their treatment is then subsidised by the research funder. Currently, this study has funding to subsidise 13 participants to be involved.

The patient and her partner (if she has one) are treated clinically in exactly the same way as a patient (couple) undergoing egg sharing for a donation of eggs to another patient or couple. The preparatory stages include extensive screening tests and mandatory counselling.

Patients then receive medications to enable their ovaries to produce several eggs at once, and the eggs are collected surgically. If the patient produces 6 or more eggs, then half will be allocated for use in research and half will be kept by the patient for their own treatment. If 5 or fewer eggs are collected, then none are used for research and the patient keeps them all.

What are the possible benefits and risks of participating?
There are no benefits to participation. The aim is to increase knowledge that might help other people in future.

The success rates of treatment may be lower because not all of the eggs collected are used in the patient's treatment. This risk is minimised by having a threshold number of eggs (6) required for the sharing arrangement to go ahead.

Where is the study run from?
The Centre for Reproductive Medicine, University Hospitals Coventry and Warwickshire NHS Trust (UK)

When Is the study starting and how long is it expected to run for?
From August 2018 to March 2026

Who is funding the study?
Pilot funding for 3 patients provided by the WPH Charitable Foundation (UK), and further funding for an additional 10 patients provided by the Wellcome Trust (UK)

Who is the main contact?
Professor Geraldine Hartshorne, geraldine.hartshorne@warwick.ac.uk

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
255896

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 255896

Study information

Scientific Title
Establishing a programme of egg sharing to research

Study objectives
This is a non-interventional trial allowing patients to opt in to sharing their eggs with a research study (IRAS 65414) during the course of an IVF treatment cycle. This trial will demonstrate the feasibility and supply of high-quality eggs from this source to support current and future research grant applications.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 28/02/2019, West Midlands - Coventry & Warwickshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 1048013; coventryandwarwick.rec@hra.nhs.uk), ref 19/WM/0003

Study design
Single-centre non-interventional study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
In vitro fertilization (IVF), infertility, miscarriage, chromosomal anomalies arising in female meiosis such as Trisomy 21 Down syndrome, mosaicism

Interventions
Patients taking part in this study are undergoing a cycle of IVF treatment. If they participate in the study, they agree to provide half of the eggs that they produce to a research project, while the other half are used in their own treatment. The patient's treatment in all other respects proceeds as normal, with a financial subsidy from the research funder. The eggs allocated for research use are used in a laboratory study (IRAS 65414) under HFEA licence (R0155).

Intervention Type
Procedure/Surgery

Primary outcome(s)
Feasibility and supply of high-quality eggs from this source to support current and future research grant applications assessed from egg numbers received measured using clinical records at the time of egg collection for each patient, research projects undertaken measured using publication records and degree completions at the study end date, and grant applications received measured using financial records at the study end date

Key secondary outcome(s))
Pregnancy occurrence and outcome in participants following IVF treatment, assessed from clinical follow-up at the end of the patient’s treatment cycle (pregnancy test), live birth (at approximately 9 months after the end of the treatment cycle), and the study end date

Completion date
30/03/2026

Eligibility

Key inclusion criteria
The inclusion criteria are the same as those applied clinically for patients sharing eggs with another person/couple.

1. Aged between 18 and 32 years
2. Normal ovarian reserve as determined by basal Follicle Stimulating Hormone (FSH) and estradiol (E2), antral follicle count, and anti-mullerian hormone (AMH) test
3. No hydrosalpinges
4. No large endometriotic ovarian cysts >3 cm
5. Body mass index between 19 and 30 kg/m²
6. Completed donor screening (transmissible diseases excluded, cytogenetic testing, and no family history of inherited disease)
7. No previous evidence of poor ovarian response
8. Informed consent provided
9. Independent counselling
10. No genetic disorder or history of recurrent miscarriage (≥3)
11. Normal serum AMH
12. No evidence of adverse embryology in previous cycle (e.g. poor embryo or oocyte quality)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
32 years

Sex
Female

Key exclusion criteria
The exclusion criteria are the same as those applied clinically for patients sharing eggs with another person/couple.
1. Not in the required age range or BMI range
2. History of previous poor ovarian response or evidence of low ovarian reserve
3. Previous pregnancy loss due to fetal abnormality
4. Family history of inherited disease
5. Positive test results for viral risks (Human Immunodeficiency Virus [HIV], Hepatitis B, Hepatitis C, or Zika virus) or transmissible diseases
6. Medical contraindication to ovarian stimulation or oocyte recovery
7. Hydrosalpinges or large endometriotic ovarian cysts
8. Previous history of adverse embryology
9. Unwilling to have all screening tests
10. Unwilling to have independent counselling
11. Unwilling to consent to the research project

Date of first enrolment
01/08/2019

Date of final enrolment
30/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Centre for Reproductive Medicine
University Hospitals Coventry and Warwickshire NHS Trust
Clifford Bridge Road
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Sponsor information

Organisation
University of Warwick

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Charity

Funder Name
WPH Charitable Trust

Alternative Name(s)
W P H Charitable Trust, Warwickshire Health Charity

Funding Body Type
Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will become available upon request from Professor Andrew McAinsh (a.d.mcainsh@warwick.ac.uk) for fully anonymised laboratory datasets only, once the research team has completed its study and published the results, after the conclusion of the research grant in 2024. If the data are not already in the public domain, data will be shared for further research to be conducted by bona fide researchers, within the terms of reference of the University of Warwick's and The Wellcome Trust's research governance procedures. Requests for clinical imaging data should be made to Professor Geraldine Hartshorne (Geraldine.hartshorne@uhcw.nhs.uk) to ensure compliance with NHS research governance for patient confidentiality and ethical approvals.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results	non-peer-reviewed first results in preprint	17/07/2020		No	No