ISRCTN11635332 https://doi.org/10.1186/ISRCTN11635332

New measurements of human sperm motility as a prediction of fertility

Submission date	Recruitment status	[_] Prospectively registered
02/10/2026	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/10/2026	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/10/2026	Urological and Genital Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
To fertilize the egg, sperm must accomplish several complicated tasks and only display many of their skills once inside the female genital tract. Activation of motility, swimming at low and high viscosity, navigation, and a particularly intense movement called hyperactivation are all thought to be crucial for natural and at a lesser level, for IVF fertility success.

This means that the detail of how a sperm swims is a key potential diagnostic factor. In this trial the Birmingham team are deploying a novel software system that analyses videos of the sperm observed on the microscope in routine practice for fertility assessment and treatment. The study will then examine whether the detailed AI analysis of the sperm motility can be correlated to the reproductive outcomes for the associated people having treatment. There are no additional interventions in treatment - nothing happens differently to them - but we hope that analysis of the data afterwards will allow us to identify certain critical sperm movement factors that would inform future trials, changing the treatment people received and reducing the chance of inappropriate treatments not working.

The aim is to discover whether newly created software that can measure details of sperm tail beat is a better diagnostic of fertility potential and outcomes than simple sperm counts.

Who can participate?
All individuals undergoing fertility treatments in participating sites that have swimming sperm.

What does the study involve?
There is no change to any treatment or care, video observations of sperm motility in the laboratory prepared sperm will be analysed and compared to the outcomes of treatment.

What are the possible benefits and risks of participating?
No risks or benefits to the participants, but you will be part of a study that may help people in the future.

Where is the study run from?
The study is being led from the Centre for Human Reproductive Science at the University of Birmingham and Birmingham Women’s Hospital (UK).

When is the study starting and how long is it expected to run for?
October 2026 to September 2030.

Who is funding the study?
Birmingham Women's and Children's NHS Foundation Trust (UK).

Who is the main contact?
Professor Jackson Kirkman-Brown, j.kirkmanbrown@bham.ac.uk
Dr Meurig Gallagher, m.t.gallagher@bham.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Jackson Kirkman-Brown

ORCID ID
https://orcid.org/0000-0003-2833-8970

Contact details
Centre for Human Reproductive Science
College of Medicine & Health
The University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT
-
j.kirkmanbrown@bham.ac.uk

Type(s)
Scientific

Contact name
Dr Meurig Gallagher

ORCID ID
https://orcid.org/0000-0002-6512-4472

Contact details
Centre for Human Reproductive Science
College of Medicine & Health
The University of Birmingham
Edgbaston
Birmingham

United Kingdom
B15 2TT
-
m.t.gallagher@bham.ac.uk

Type(s)
Public

Contact name
None - RESEARCH NURSE

Contact details
Birmingham Women's Hospital
R&D Gynae Team
Birmingham
United Kingdom
B15 2TG
+44 7469 375 162
researchdonor@bham.ac.uk

Additional identifiers

Study information

Scientific Title
MotilitY diagnostics in Insemination – The My-I Project

Acronym
My-I

Study objectives
My-I is a multi-centre, multi-country evaluation of the potential of sperm flagellar movement as a novel prognostic in ART outcome. The primary objective of the clinical project is to determine whether there is a useful prognostic link between flagellar motility where the primary outcome measure is determination of the impact of the intervention on CPR based on detection of fetal heartbeat and/or fetal sac at 6-9 weeks' gestation.

Secondary objectives will include LBR ≥37 weeks' gestation, miscarriage rate defined as pregnancy loss after confirmation of clinical pregnancy; and conception or fertilisation rates.

Ethics approval required
Ethics approval not required

Ethics approval(s)

Primary study design
Observational

Secondary study design

Case series

Study type(s)

Health condition(s) or problem(s) studied
Fertility; infertility; semen analysis; sperm testing

Interventions
No randomisation will occur in this project, all participants follow the standard care clinical treatment pathway as comparable patients not in the study, just with anonymised post-hoc analysis as outlined in the trial protocol.

The only difference being that My-I will incorporate the analysis of microscopy videos of sperm in existing ART preparations.

Intervention Type
Other

Primary outcome(s)
1. Successful fertility treatment measured using Clinical Pregnancy Rate = fetal heartbeat and/or fetal sac at 6-9 weeks' gestation

2. Conception rates (biochemical), Live Birth Rate = LBR ≥37 weeks' gestation or Miscarriage rate (CPR not reaching LBR) measured using patient reported / clinic recorded at ≥37 weeks' gestation

3. Laboratory embryology parameters as available measured using fertilisation rates, embryo grade, embryo euploidy (where available), related scores (e.g. by AI where available) at Embryology laboratory Day zero to Day seven

Key secondary outcome(s)

Completion date
01/09/2030

Eligibility

Key inclusion criteria
My-I will take data from multiple leading ART assisted conception units across the world. All participating sites will be recognised teaching institutions (or equivalent) accredited in the performance of ART fertility treatments and have been initially selected on the basis of potentially high-quality data provision, with sufficient patient throughput.
1. Couples/individuals able to provide informed consent (where required)
2. Couples/individuals undergoing ART procedure
3. Female:
3.1. Age: 18+ years
4. Male/donor:
4.1. Age: 18+ years
4.2. Motile sperm available for the treatment cycle
4.3. For couples or individuals using donor sperm, consent of the female partner is all that is required (donor consent not required)

4.4. For couples or individuals using donor oocytes, consent of the partner providing the sperm is all that is required (if donor sperm no consent required)

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Couples/individuals who have not consented prior to ART procedure will be ineligible (where consent is required)

Date of first enrolment
01/10/2026

Date of final enrolment
31/12/2029

Locations

Countries of recruitment
United Kingdom

England

Australia

Belgium

Greece

South Africa

Study participating centre
Birmingham Women's Fertility Centre
Birmingham Women's Hospital

Mendelssohn Drive
Edgbaston
Birmingham
England
B15 2TG

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type

Funder Name
Birmingham Women's and Children's NHS Foundation Trust

Alternative Name(s)
BWC

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available