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A cohort study of pregnancy outcome in couples who miscarry

Submission date
28/02/2017

Recruitment status
No longer recruiting

Registration date
14/03/2017

Overall study status
Ongoing

Last Edited
24/10/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Miscarriage is a term given to the loss of a baby during the first 23 weeks of pregnancy. In the UK, the term 'recurrent miscarriage' means having three or more miscarriages (even if you have successful pregnancies in between).

Recurrent miscarriage is a distressing problem for which there is no effective preventative treatment currently. To develop new treatments, we need to identify couples at high risk of future pregnancy loss. There is limited evidence assessing the predictive power of current tests and risk factors, such as a history of pregnancy loss and body mass index (BMI). There have been very few long-term follow-up studies with accurate recording of future pregnancy outcomes. This study uses digital technology to collect and analyse information about the patient's history and investigation results, and link these to pregnancy and neonatal outcomes. This study aims to undertake a large study of pregnancy outcomes following miscarriage.

Who can participate?
Patients and their partner (where applicable) who have suffered a miscarriage.

What does the study involve?
After consenting to take part, participants and their partners are asked to complete a questionnaire about their previous experiences with pregnancy loss and have their medical records reviewed to find out about their medical history. Every 6 months, couples are asked to fill in follow-up questionnaires about whether they have had any reproductive treatment and if that has led to a successful pregnancy and birth. Information collected in this study is then used to identify couples at risk of pregnancy loss and to predict pregnancy outcomes.

The cohort study is part of a miscarriage platform that will test multiple treatments and provide more timely answers to whether interventions are effective. Participants and their partner (where applicable) joining the cohort study will also be asked to give consent to participate in the control arm (no treatment) of any future trials that will be conducted by the research team. If the participant is allocated to the intervention group of a future trial, they will be asked to provide their consent before taking the intervention.

Consent will also include the option to be contacted about future related studies and/or possible retrieval of health information from their NHS electronic health 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?
University of Birmingham, UK.

When is the study starting and how long is it expected to run for?
April 2016 and is ongoing, subject to funding

Who is funding the study?
Tommy’s Baby Charity (UK)

Who is the main contact?
Mr Lee Priest, tommys@contacts.bham.ac.uk; l.priest.1@.bham.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Mr Lee Priest

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
213740

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A cohort study in couples who have suffered miscarriage with assessment of future pregnancy outcome

Acronym
Tommy's Net

Study objectives
Current study objectives as of 22/10/2025:
Some women experience miscarriage, which can increase the risk of subsequent miscarriages. Recurrent miscarriage is a debilitating disorder for which there is no effective medical intervention. To develop new interventions, we need to identify couples at high risk of future pregnancy loss. There is little published data that assesses the prognostic use of current tests and risk factors such as pregnancy loss history and BMI. There have been very few long-term follow-up studies with accurate recording of future pregnancy outcomes. This study is using digital technology to collect and analyse information about the patient's history, investigation results and link these to pregnancy and neonatal outcome. This study aims to undertake a large cohort study of pregnancy outcomes following miscarriage.

Previous study objectives:
Some women experience recurrent miscarriage, in which they experience three or more miscarriages in a row. Recurrent miscarriage is a debilitating disorder for which there is no effective medical intervention. To develop new interventions, we need to identify couples at high risk of future pregnancy loss. There is little published data that assesses the prognostic use of current tests and risk factors such as pregnancy loss history and BMI. There have been very few long-term follow-up studies with accurate recording of future pregnancy outcomes. This study is using digital technology to collect and analyse information about the patient's history, investigation results and link these to pregnancy and neonatal outcome. This study aims to undertake a large cohort study of pregnancy outcomes following miscarriage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 09/03/2017, West Midlands Research Ethics Committee (Health Research Authority, Ground Floor, Skipton House, 80 London Road, London SE1 6LH; +44 (0)207 104 8193; NRESCommittee.WestMidlands-Edgbaston@nhs.net), ref: 17/WM/0050
2. Amended 11/05/2020, West Midlands Research Ethics Committee (Health Research Authority, Ground Floor, Skipton House, 80 London Road, London SE1 6LH; +44 (0)207 104 8193; edgbaston.rec@hra.nhs.uk), ref: 17/WM/0050, amendment ref: AM04

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Miscarriage

Interventions
Current interventions as of 22/10/2025:
Potential participants (which may or may not include couples) will be referred to a miscarriage clinic by their GP or self-refer. The site can provide an information letter by paper or online via email and/or text, but email will be used wherever possible. The local research team (care team) may provide information regarding standard care NHS services, along with a link to the online study patient information sheet (PIS), enrolment form and consent form.

To gain a better understanding of the impact that male factors, especially sperm, play in miscarriage risk, partners will have the same opportunity to enrol in the study. Not all partners are male, and not all partners are biologically linked to a pregnancy. In this context, the term 'partner' refers to the person whose sperm was involved in the pregnancies.

Once the enrolment form and consent form have been completed, the participant and partner (where applicable) will be able to access the baseline questionnaire. The baseline questionnaire documents the health and pregnancy status and any standard care received up to this point. A follow-up questionnaire is six-monthly after the date of the baseline questionnaire and completed by participants and partners (where applicable) up to 5 years. The follow-up questionnaire will document further reproductive treatment and pregnancy outcomes. The data will be stored in a secure study database held on Birmingham Clinical Trials Unit (BCTU) servers, University of Birmingham. All existing relevant investigation results may be imported or input into the database from existing hospital systems

Personal data recorded on all documents will be regarded as strictly confidential and will be handled and stored in accordance with the Data Protection Act 2018 (and subsequent amendments). The baby’s NHS number and future relevant contact with the participant (or partner, where applicable) will be requested through appropriate consent so that follow-up of the baby’s development could be facilitated. Information regarding the baby's developmental follow-up may also be requested from GP records using data linkage. The consent form will ask participants to consider providing consent to be contacted in the future about possible studies.

Previous interventions:
Couples will be asked to fill in clinical history sheets prior to clinic visits. When they arrive at the clinic, a member of the research team will explain Tommy’s Net and ask them to consent to the study. If they consent, they will be asked permission to have their data entered into a bespoke server and database. This system will then also import the results of investigations and reproductive outcomes. Couples will be contacted every 6 months for details of further reproductive treatment and pregnancy outcomes. The baby’s NHS number will be requested through appropriate consent so that follow-up of the baby’s development can be facilitated. Information regarding the baby's developmental follow-up will be requested from GP records using data linkage.

Intervention Type
Other

Primary outcome(s)
Live birth rate is assessed by patient questionnaire and data linkage at 6-month intervals until family is complete and child is aged 5 years.

Key secondary outcome(s))
1. Miscarriage rate is assessed by patient questionnaire and data linkage at 6-month intervals until family is complete
2. Type of miscarriage is assessed by patient questionnaire and data linkage at 6-month intervals until family is complete
3. Obstetric complications are assessed by patient questionnaire and data linkage at 6-month intervals until family is complete
4. Neonatal complications are assessed by patient questionnaire and data linkage at 6-month intervals until family is complete

Completion date
01/04/2026

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 22/10/2025:
1. History of one or more pregnancy losses
2. Aged 16 years or over
3. Actively trying to become pregnant
4. Willing and able to provide consent

Previous key inclusion criteria:
1. Couples with a history of one or more pregnancy losses
2. Aged 18-55 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Sex
All

Key exclusion criteria
Current key exclusion criteria as of 22/10/2025:
Decline to consent to having their information stored

Previous key exclusion criteria:
Couples who decline to give consent

Date of first enrolment
01/04/2017

Date of final enrolment
01/04/2022

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Birmingham Women's Hospital Foundation Trust
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2TG

Study participating centre
Imperial College Healthcare NHS Trust
Hammersmith Hospital Campus
Du Cane Road
London
United Kingdom
W12 0NN

Study participating centre
Ashford and St Peter's Hospitals NHS Foundation Trust
St Peters Hospital
Guildford Road
Chertsey
United Kingdom
KT16 0PZ

Study participating centre
The Shrewsbury and Telford Hospital NHS Trust
Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ

Study participating centre
East Lancashire Hospitals NHS Trust
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
University Hospital of Hartlepool
Holdforth Road
Hartlepool
United Kingdom
TS24 9AH

Study participating centre
NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Wirral University Teaching Hospital NHS Foundation Trust
Arrowe Park Hospital
Arrowe Park Road
Upton
Wirral
United Kingdom
CH49 5PE

Study participating centre
East Suffolk and North Essex NHS Foundation Trust
Colchester Dist General Hospital
Turner Road
Colchester
United Kingdom
CO4 5JL

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
North Tees and Hartlepool NHS Foundation Trust
University Hospital of Hartlepool
Holdforth Road
Hartlepool
United Kingdom
TS24 9AH

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Tommy's Baby Charity

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing plan as of 22/10/2025:
The participant-level data will be stored on the secure BCTU servers. The University of Birmingham has Data Protection Registration to cover the purposes of analysis and for the classes of data requested. The University's Data Protection Registration number is Z6195856. Personal data recorded on all documents will be regarded as strictly confidential and will be handled and stored in accordance with the Data Protection Act 2018 (and subsequent amendments).

The underlying principle of Tommy's National Centre for Miscarriage Research is that data stored within Tommy's Net is made available to all the research centres that have been approved by the responsible ethics committee. This provides a reciprocal arrangement whereby anonymised data can be uploaded to Tommy's Net and then shared between all approved parties. The aim is to ensure that researchers do not have access to personal identifiers through

these data. Tommy's Net is ongoing but requests for data generated during this study will be considered by the Tommy's Data Sharing Committee. Only scientifically sound proposals from appropriately qualified research groups will be considered for data sharing. The request will be reviewed in accordance with the data sharing policies of the University of Birmingham and in discussion with the CI and, where appropriate (or in the absence of the CI), any of the following: the Trial Sponsor, the relevant Study Management Group (SMG), and the independent TSC of any sub-studies conducted.

A formal Data Sharing Agreement (DSA) may be required between respective organisations once the release of the data is approved and before the data can be released. Data will be fully de-identified (anonymised). Any data transfer will use a secure and encrypted method.

Previous IPD sharing plan:
The participant level data will be stored on on the secure, NHS, N3 encrypted system in a server in UHCW access to this will be controlled to met with information governance standards as laid down in the Information Goverance Tool Kit.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Associations with dietary patterns	26/11/2024	03/12/2024	Yes	No
Results article	Fertility, time to pregnancy, and pregnancy outcomes	26/06/2025	18/07/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes