ISRCTN17732518 https://doi.org/10.1186/ISRCTN17732518

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
03/12/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Current plain English summary as of 18/09/2020:
Background and study aims
Miscarriage is a term given to the loss of a baby during the first 23 weeks of pregnancy. Some women experience recurrent miscarriage, in which they experience three or more miscarriages in a row. Recurrent miscarriage is a distressing problem for which there is no effective preventative treatment currently. In order to develop new treatments, we need to identify couples at high risk of future pregnancy loss. There is little evidence that assesses the predictive power of current tests and risk factors, such as pregnancy loss history and body mass index (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 and investigation results and link these to pregnancy and neonatal outcome. The aim of this study is to undertake a large study of pregnancy outcome following miscarriage.

Who can participate?
Couples who have suffered miscarriage.

What does the study involve?
After agreeing to take part, women 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 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.
Participants will also be offered the opportunity to give their consent to take part in future Cohort Multiple Randomised Controlled Trials (cmRCT). Participants will agree to participate in the control (no treatment) arm 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 prior to taking the intervention.

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?
1. University Hospitals Coventry and Warwickshire NHS Trust (UK)
2. Birmingham Women's Hospital Foundation Trust (UK)
3. Imperial College Healthcare NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2016 to April 2026

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

Who is the main contact?
Professor Siobhan Quenby
s.quenby@warwick.ac.uk

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Previous plain English summary:
Background and study aims
Miscarriage is a term given to the loss of a baby during the first 23 weeks of pregnancy. 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. In order 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. The aim of this study is to undertake a large cohort study of pregnancy outcome following miscarriage.

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Professor Siobhan Quenby
s.quenby@warwick.ac.uk

Contact information

Type(s)
Public

Contact name
Prof Siobhan Quenby

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s.quenby@warwick.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number
213740

ClinicalTrials.gov number

Secondary identifying numbers
IRAS 213740

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

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. In order 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. The aim of this study to undertake a large cohort study of pregnancy outcome 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 reference AM04

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

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 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 could be facilitated.

Information regarding the babies developmental follow up will be requested from GP records using data linkage.

Intervention Type
Other

Primary outcome measure
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.

Secondary outcome measures
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

Overall study start date
01/04/2016

Completion date
01/04/2026

Eligibility

Key inclusion criteria
1. Couples with a history of one or more pregnancy losses
2. Aged between 18-55

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
9000

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
England

United Kingdom

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

Sponsor information

Organisation
University Hospitals Coventry and Warwickshire NHS trust

Sponsor details
Clinical Sciences Research Laboratories
Coventry
England
United Kingdom
CV2 2DR

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/025n38288

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

Publication and dissemination plan
Planned publications will occur at annual intervals in high-impact peer reviewed journals.

Intention to publish date
01/04/2027

Individual participant data (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 repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article	Associations with dietary patterns	26/11/2024	03/12/2024	Yes	No