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The optimal management in monochorionic twins (OMMIT) study

Submission date
12/04/2016

Recruitment status
No longer recruiting

Registration date
22/04/2016

Overall study status
Completed

Last Edited
02/01/2020

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Monochorionic diamniotic (MCDA) twin pregnancy is where a woman is pregnant with twins who share a single placenta. This type of pregnancy is very high-risk, as it can result in fatal complications such as twin-twin transfusion syndrome, TTTS (a condition where blood flows unevenly between the babies). This is thought to happen because inter-twin placental anastomoses (connections between arteries and veins) can form, causing a significant change in the blood pressures of the twins as one twin "donates" a significant proportion of its blood to the other "recipient" twin. The donor twin may then go into kidney failure and produce very little amniotic fluid (fetal urine), and the recipient twin produces too much amniotic fluid and may go into heart failure. Without treatment, 90% of these pregnancies will miscarry before 26 weeks. However, there is an effective treatment for TTTS called fetoscopic laser ablation (FLA) which involves inserting a small camera into the amniotic fluid sac of the recipient twin and burning the vascular anastomoses on the surface of the placenta, to block these connections and attempt to rebalance the blood flow between the twins. In 85% cases treated by FLA at least one twin will survive, in 40% of cases 2 twins will survive. The aim of this study is to develop a model to predict which MC twin pregnancies will develop complications later in pregnancy. The project takes place in two parts, the first part looking back on women who previously had an MCDA pregnancy, and the second part looking at women who are currently experiencing a MCDA pregnancy.

Who can participate?
In the first part of the study, women who had MCDA pregnancies and had samples of blood and information about the result of their pregnancy stored. In the second part of the study, women aged 18-50 who book at Birmingham Women's Hospital with MC twin pregnancies (cohort C) and those who are referred to Birmingham Women's Hospital for assessment of treatment of complications of MC twin pregnancies (cohort S) can participate.

What does the study involve?
In the first part of the study, the researchers look at any chemical indicators (biomarkers) of angiogenesis (new blood vessel formation) and the function of the placenta in previously stored blood samples that were taken in the first 12 weeks of pregnancy. These are then compared to information taken from ultrasound measurements at the same time and then matched to the

outcomes (how the pregnancy progressed). In the second part of the study, there are two groups of women being examined: Cohort S and Cohort C. Women in both groups have blood samples taken at 12, 16 and 20 weeks of their pregnancy. In addition, their ultrasound results and information about the outcome of the pregnancy is also collected. For participants in cohort C (women booked to have FLA), a sample of blood and amniotic fluid, and ultrasound measurements are also taken immediately before and after they have the FLA procedure. These blood samples are then looked at in the lab to look for noteworthy biomarkers.

What are the possible benefits and risks of participating?
There are no direct benefits involved with taking part in the study. In the second study, there is a small risk that participants may experience pain, discomfort or bruising during or after blood samples are taken.

Where is the study run from?
Birmingham Women's Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2014 to October 2018

Who is funding the study?
1. The Richard and Jack Wiseman Trust (UK)
2. British Maternal and Fetal Medicine Society (UK)

Who is the main contact?
Dr Fiona Mackie

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
1

Study information

Scientific Title
Optimal Management in complicated Monochorionic Twins (OMMIT) Study

Acronym
OMMIT

Study objectives
It is possible to predict which monochorionic twin pregnancies will go on to develop complications later in pregnancy based on first-trimester maternal blood samples and ultrasound measurements.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. East Midlands - Derby Research Ethics Committee, 09/06/2015, ref: 15/EM/0240 (OMMIT 1)
2. East Midlands - Derby Research Ethics Committee, 01/07/2015, ref: 15/EM/0244 (OMMIT 2)

Primary study design
Observational

Study design
Observational single-centre study in two parts: a retrospective study (OMMIT 1) and a prospective study (OMMIT 2)

Study type(s)
Screening

Health condition(s) or problem(s) studied
Complications of monochorionic (MC) twin pregnancies including twin-twin transfusion syndrome (TTTS), twin anaemia-polycythaemia sequence (TAPS), selective intrauterine growth restriction (sIUGR) and single intrauterine fetal demise (sIUFD)

Interventions
There are two parts to this trial: a retrospective study and a prospective study.

In the retrospective study (OMMIT 1), markers of angiogenesis (blood vessel developmental) and placental function in the stored first-trimester blood samples will be analysed, these will then be combined with first-trimester ultrasound measurements and matched to outcome data to attempt to create a model.

In the prospective study (OMMIT 2), there will be 2 cohorts: Cohort S and Cohort C.
Cohort S will have blood samples taken at 12, 16 and 20 weeks gestation, their ultrasound measurements will be recorded and their outcomes collected. Cohort C will have a maternal blood sample pre- FLA and post-FLA. Amniotic fluid samples will be collected immediately pre-FLA and post-FLA, and ultrasound measurements. Researchers will use the results of the retrospective study to decide which biomarkers to investigate in the blood and amniotic fluid samples.

The following will then be compared:
1. "Normal" Cohort S blood samples to Cohort C samples
2. Cohort S samples longitudinally over the 3 time points
3. Cohort C pre-FLA and post-FLA blood and amniotic fluid samples

Intervention Type
Other

Primary outcome(s)
Complication of MC pregnancy:
1. TTTS
2. Discordant growth
3. Selective IUGR
4. Single twin demise: <24 weeks, >24 weeks
5. Discordant chromosomal or structural anomaly
6. Neonatal mortality (until discharge)

These outcomes will be extracted from the hospital notes using a specially designed data collection form and recognised definitions of conditions where appropriate.

Key secondary outcome(s)
1. Antenatal complications (e.g. antepartum haemorrhage, small for gestational age, gestational diabetes, pre-eclampsia)
2. Maternal morbidity: (e.g. sepsis, hypertension, platelet or coagulation anomaly)
3. Gestation of delivery (If preterm <37 weeks iatrogenic or spontaneous)
4. Induction (or C/S) and precipitating cause
5. Mode of delivery (and reason)
6. Admission to NICU (and indication)
7. Composite measure of maternal morbidity
8. Composite measure of neonatal morbidity

These outcomes will be extracted from the hospital notes using a specially designed data collection form and recognised definitions of conditions where appropriate.

Completion date
01/10/2018

Eligibility

Key inclusion criteria
Retrospective study
Monochorionic diamniotic (MCDA) pregnancies for which trimester blood samples and outcome data have been stored.

Prospective study
Cohort S will be patients:
1. Booking at Birmingham Women's Clinic with an MCDA pregnancy confirmed on first-trimester ultrasound
2. Less than 20+6 weeks gestation at recruitment
3. Provide valid informed consent

Cohort C will be patients:
1. Referred to Birmingham Women's Hospital for treatment of a complication of monochorionic pregnancies
2. Provide valid informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
177

Key exclusion criteria
1. Unable to provide consent
2. Unable to confirm chorionicity

Date of first enrolment
07/08/2015

Date of final enrolment
07/08/2017

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Birmingham Women's NHS Foundation Trust

ROR
https://ror.org/056ajev02

Funder(s)

Funder type
Charity

Funder Name
The Richard and Jack Wiseman Trust

Funder Name
British Maternal and Fetal Medicine Society

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/05/2019	17/05/2019	Yes	No
Results article	results	31/12/2019	02/01/2020	Yes	No
Protocol article	protocol	26/05/2017		Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No