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Reduced fetal Movements Intervention Trial

Submission date
24/08/2011

Recruitment status
No longer recruiting

Registration date
12/09/2011

Overall study status
Completed

Last Edited
11/09/2015

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
Currently, 1 in 200 babies born after 24 weeks of pregnancy is stillborn. Despite improvements in pregnancy care, the rate of stillbirth is the same as 20 years ago. One reason is the lack of a test to identify which babies are most at risk of stillbirth. One symptom that mothers are commonly aware of before stillbirth is a reduction in their baby's movements. We believe that a reduction in babies' movements is a sign that they are receiving less nutrients and oxygen from their mother because the afterbirth (placenta) is working less well. The placenta in women who come to hospital with a reduction in baby's movements is smaller, abnormally shaped and more damaged than those with normal movements. We believe that performing specialised tests on women who come to hospital because their baby's movements have reduced could identify women whose babies are at most risk of stillbirth, allowing us to deliver them before they die. The aim of our study is to find out whether recommending delivery based on extra tests reduces the number of stillbirths and admissions to the neonatal intensive care unit (NICU), compared to the current standard practice. The extra tests are assessment of the baby's size, the amount of water around the baby, the blood flow through the placenta and a blood test. By carrying out this initial study we will find out whether women will agree to participate in a study after coming to hospital with reduced baby movements and whether the tests and any associated treatment cause increased anxiety for mothers. We will also see whether the test results changed the way doctors and midwives cared for their patients. We will then be able to develop a larger study to see whether these tests can help prevent stillbirths.

Who can participate?
Women over 16 years of age who come to the maternity triage unit or maternity day unit at St Mary's Hospital, Manchester with reduced baby movements between 36 weeks and 41 weeks 3 days of pregnancy.

What does the study involve?
Women are randomly allocated into one of two groups. In the current care group the women are checked by a midwife and if they meet certain criteria we perform an ultrasound scan for the baby's size and the amount of water around the baby and the result is recorded. In the detailed assessment group the women have an ultrasound scan for the baby's size, amount of water around the baby and blood flow through the placenta, appearance of the placenta and a blood test.

What are the potential benefits and risks of participating?
The additional tests might identify women at high risk of complications, allowing the baby to be delivered earlier. There are no known risks of having an extra scan or blood test in late pregnancy.

Where is the study run from?
St Mary's Hospital, Manchester, UK.

When is the study starting and how long is it expected to run for?
November 2011 to November 2012.

Who is funding the study?
Manchester Biomedical Research Centre and Central Manchester University Hospitals NHS Foundation Trust (UK).

Who is the main contact?
Dr Alexander Heazell
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Contact information

Type(s)
Scientific

Contact name
Dr Alexander Heazell

Contact details
Maternal and Fetal Health Research Centre
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United Kingdom
M13 9WL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.41

Study information

Scientific Title

A pilot randomised controlled trial to determine whether intensive investigation for women presenting with reduced fetal movements after 36 weeks gestation reduces the incidence of poor pregnancy outcome compared to standard management.

Acronym
ReMIT

Study objectives
We hypothesise that intensive investigation of women with reduced fetal movements by ultrasound scan measurement of the baby's size, liquor volume, detailed assessment of the placenta and with measurement of the placental marker, human placental lactogen (hPL) will improve prediction of poor pregnancy outcome, and that recommendation of delivery based on these indices will reduce the incidence of poor pregnancy outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
United Kingdom National Research Ethics Service, NRES Committee North West - Greater Manchester Central Committee

Study design
Single-centre non-blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Stillbirth, Perinatal Death

Interventions
Intervention Group - intensive investigation specifically ultrasound assessment of estimated fetal weight, liquor volume, umbilical artery Doppler and measurement of human placental lactogen with recommendation to deliver the infant if any of these indices are abnormal.

Control Group - standard treatment as outlined in the guidelines from the Royal College of Obstetricians and Gynaecologists.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Proportion of women with poor pregnancy outcome
2. Poor pregnancy outcome is defined as:
2.1. Stillbirth
2.2. Unexpected admission to the neonatal intensive care unit
2.3. Metabolic acidosis (umbilical arterial cord pH <7.1)

Secondary outcome measures
1. Proportion of infants with a birthweight centile < 10
2. Proportion of eligible women recruited to the study (feasibility)
3. Anxiety scores and views of women before and after their assigned treatment (acceptability)
4. Views of medical and midwifery staff on the intervention

Overall study start date
01/11/2011

Completion date
01/11/2012

Eligibility

Key inclusion criteria
Women presenting with a subjective reduction in fetal movements between 36+0 and 41+3 weeks gestation with a viable singleton pregnancy on initial assessment.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
120

Key exclusion criteria
1. Fetus with a congenital anomaly
2. Multiple pregnancy
3. Fetus requiring immediate delivery for abnormal fetal heart rate trace
4. Maternal age <16 years
5. Women unable to give informed consent

Date of first enrolment
01/11/2011

Date of final enrolment
01/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Mary's Hospital
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Central Manchester University Hospitals NHS Foundation Trust (UK)

Sponsor details
Research and Innovation Directorate
1st Floor
Postgradute Centre
Oxford Road
Manchester
England
United Kingdom
M13 9WL

Sponsor type
Hospital/treatment centre

Website
http://www.cmft.nhs.uk/

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Manchester Biomedical Research Centre (UK)

Funder Name
Central Manchester University Hospitals NHS Foundation Trust (UK) (ref: R01519)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/04/2013		Yes	No