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Amnio infusion in preterm premature rupture of membranes

Submission date	Recruitment status	[X] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/04/2016	Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims
Preterm premature rupture of membranes (PPROM) is a condition where a pregnant woman's waters break very early in the pregnancy (i.e., before 37 weeks). The amniotic fluid, which surrounds and protects the fetus in the womb, leaks out through the vagina. If PPROM occurs, there is an increased risk of premature delivery and its associated complications, including death of the premature infant. The aim of this study is to find out whether intervention for PPROM can improve outcomes.

Who can participate?
Pregnant women with preterm premature rupture of membranes

What does the study involve?
Participants are randomly allocated to either undergo amnioinfusion (putting fluid back into the womb) or expectant management (watch and wait). The treatment takes place in hospital as an outpatient, although sometimes admission to hospital may be necessary. In the amnioinfusion group, amniotic fluid is replaced weekly until 34 weeks if needed. In the expectant management group, the pregnancy is monitored by weekly scans but no fluid is replaced. The short-term outcomes to be assessed are the number of infant deaths before hospital discharge and infant breathing difficulties, defined as needing oxygen at 28 days after delivery. We test the surviving infants' lung function and development up to two years of age.

What are the possible benefits and risks of participating?
Not provided at time of registration

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

When is the study starting and how long is it expected to run for?
October 2007 to October 2014

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Dr Devender Roberts

Contact information

Type(s)
Scientific

Contact name
Dr Devender Roberts

Contact details
Fetal Centre
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L8 7SS

Additional identifiers

Protocol serial number
HTA 07/39/01; N0128129813

Study information

Scientific Title
Amnio infusion in preterm premature rupture of membranes (AMIPROM study)

Acronym
AMIPROM

Study objectives
The aim of this project is to study whether intervention for premature rupture of membranes (PROM) improves the outcome for babies. The study will compare the neonatal, maternal and pregnancy outcomes in pregnancies with very early PROM managed expectantly or managed with serial amnioinfusions.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/073901
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0006/51828/PRO-07-39-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design

Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pregnancy and Childbirth: Preterm premature rupture of membranes

Interventions
Randomised controlled trial. Women with very early premature rupture of membranes will be randomised into (a) expectant management or (b) serial amnioinfusions.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The study will compare the neonatal, maternal and pregnancy outcomes in pregnancies with very early PROM managed expectantly with those managed with serial amnioinfusions (replacement of fluid into the amniotic sac).

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/10/2014

Eligibility

Key inclusion criteria
15 women with premature rupture of membranes in each arm

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Not provided at time of registration

Date of first enrolment

01/10/2007

Date of final enrolment
31/10/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Liverpool Women's Hospital
Liverpool
United Kingdom
L8 7SS

Sponsor information

Organisation
Liverpool Women's NHS foundation Trust (UK)

ROR
https://ror.org/04q5r0746

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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	pilot results	01/04/2013		Yes	No
Results article	results	01/04/2014		Yes	No
Results article	results	01/05/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes