

Amnio infusion in preterm premature rupture of membranes

Submission date 30/09/2004	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/04/2016	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

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 PPRM 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 PPRM 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
Liverpool Women's Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

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

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 measure

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).

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/2007

Completion date

31/10/2014

Eligibility

Key inclusion criteria

15 women with premature rupture of membranes in each arm

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

15

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**

England

United Kingdom

Study participating centre

Liverpool Women's Hospital

Liverpool

United Kingdom

L8 7SS

Sponsor information**Organisation**

Liverpool Women's NHS foundation Trust (UK)

Sponsor details

Crown Street

Liverpool

England
United Kingdom
L8 7SS

Sponsor type

Hospital/treatment centre

Website

<http://www.lwh.me.uk/>

ROR

<https://ror.org/04q5r0746>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

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	pilot results	01/04/2013		Yes	No
Results article	results	01/04/2014		Yes	No
Results article	results	01/05/2014		Yes	No