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Prenatal treatment of Lower Urinary Tract Obstruction

Submission date	Recruitment status	[_] Prospectively registered
28/04/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/08/2017	Neonatal Diseases	

Plain English summary of protocol

Background and study aims
Fetal bladder outflow obstruction is a rare condition where an unborn baby (fetus) is unable to pass urine due to a blockage of the tube called the urethra. This may cause permanent damage to the baby's kidneys and can lead to poor lung development and physical deformities such as clubfoot. About half of the babies diagnosed with this problem before birth will die either before birth or in the newborn period. For several years, vesico-amniotic shunting has been offered as a treatment to relieve the obstruction. A vesico–amniotic shunt is a tube that it is inserted into the unborn baby’s bladder to drain the excess fluid. However, there is only weak evidence that it improves survival and kidney function in those treated. The aim of this study is to find out whether vesico-amniotic shunting improves outcomes for fetal bladder outflow obstruction.

Who can participate?
Fetuses with bladder outflow obstruction

What does the study involve?
Following an ultrasound diagnosis of fetal bladder outflow obstruction, the fetuses are randomly allocated to either receive a vesico-amniotic shunt or continue with conservative treatment without a shunt. Termination and miscarriage rates, survival, and bladder and kidney function are assessed at 4 - 6 weeks and 12 months, and continence is assessed at 5 years.

What are the possible benefits and risks of participating?
This study is a crucial step in establishing whether this procedure has a place in future fetal medicine practice.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
September 2005 to September 2018

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

Who is the main contact?
Prof. Mark Kilby
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Study website
http://www.pluto.bham.ac.uk/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 07/01/44; NN3007

Study information

Scientific Title
A multi-centre randomised controlled trial comparing intra-uterine vesico-amniotic shunting versus not shunting in the treatment of congenital bladder outflow obstruction

Acronym
PLUTO

Study objectives

Does intra-uterine vesico-amniotic shunting for fetal bladder outflow obstruction improve perinatal morbidity and mortality in fetuses, compared to conservative management?

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/070144
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/51741/PRO-07-01-44.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee 2, January 2005, ref: 04/Q2404/89

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
Patient information material can be found at http://www.pluto.bham.ac.uk/trial/Patient.htm.

Health condition(s) or problem(s) studied
Congenital bladder outflow obstruction

Interventions
Fetal vesico-amniotic shunt versus no shunt.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Perinatal mortality rates and renal function at 4 - 6 weeks and 12 months measured via:
1. Serum creatinine
2. Renal ultrasound
3. Need for dialysis/transplant

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/09/2005

Completion date
30/09/2018

Eligibility

Key inclusion criteria
Mother:
1. Written informed consent given
2. Able to understand information provided (use of interpreter may be required)
3. Singleton pregnancy

Foetus:
1. Evidence of bladder outflow obstruction from ultrasound imaging
2. No major extra genitourinary anomalies present

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
200

Key exclusion criteria
Additional major structural or chromosomal anomaly

Date of first enrolment
01/09/2005

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TG

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Edgbaston
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United Kingdom
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Sponsor type
University/education

Website
http://www.bham.ac.uk/

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Funder Name
Wellbeing of Women (UK)

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
Not provided at time of registration

Intention to publish date
01/01/1900

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?
Protocol article	protocol	01/07/2007		Yes	No
Results article	results	02/11/2013		Yes	No
Results article	results	01/12/2013		Yes	No