PLUTO trial: Percutaneous shunting in Lower Urinary Tract Obstruction trial

Background

Fetal bladder outflow obstruction is a congenital 'blockage' of the tube connecting the bladder neck to the external part of the baby (the urethra). This may cause permanent damage to the baby's kidneys (probably due to increased pressure) and can lead to poor lung development and physical deformities such as clubfoot.

Over all, about half of babies diagnosed with this problem before birth will die, either before birth or in the newborn period. For several years, treatment to relieve the obstruction (vesico-amniotic shunting) has been offered, but with only weak evidence that it improves survival and kidney function in those treated.

What was the PLUTO Trial?

Following an ultrasound diagnosis of fetal bladder outflow obstruction, eligibility and baseline characteristics were confirmed by standard assessments of renal function, a detailed ultrasound examination to exclude other co-existing anomalies and fetal karyotyping. If the mother consented to participation, the fetus was randomised to receive either a fetal vesico-amniotic shunt or continue with conservative management without a shunt.

The aim was to randomise 200 pregnancies from across the UK. The primary outcome measures were perinatal mortality and serum creatinine at 6 weeks of age. Secondary outcome measures included bladder and renal function, termination and miscarriage rates and resource usage. Initial follow-up of secondary outcomes continued to one year of age. Long-term follow-up of continence is planned at five years.

What did the study find?

The PLUTO trial randomised 31 pregnancies and collected information from another 46 pregnancies where the parents or clinicians elected for one management pathway or the other. The reasons we suspect contributed to slow recruitment were a lower than expected prevalence of fetal bladder obstruction, strong preferences for one option by the fetal medicine specialists and parents opting for termination of pregnancy upon diagnosis.

A parallel study involved parents who consented to the trial, opted for one treatment or opted for termination. These were approached for an interview to discuss their reasons for that choice. The results of the trial are currently being analysed and will be published in 2012.

What impact will this study have?

As fetal bladder outlet obstruction is a relatively uncommon condition, this multicentre trial has assessed the short and long-term effects of this intervention. This is a crucial step in establishing whether this procedure has a place in future fetal medicine practice and the imminent results are highly anticipated.

Publications

- **Effectiveness of percutaneous vesico-amniotic shunting in congenital lower urinary tract obstruction: divergence in prior beliefs among specialist groups (http://www.sciencedirect.com/science/article/pii/S0301211510002149)**. Brown C, Morris RK, Daniels J, Khan KS, Lilford RJ, Kilby MD. Eur J Obstet Gynecol Reprod Biol. 2010 Sep;152(1):25-9. Epub 2010 May 23.
- **Systematic review of the effectiveness of antenatal intervention for the treatment of congenital lower urinary tract obstruction (http://www.ncbi.nlm.nih.gov/pubmed/20374578)**. Morris RK, Malin GL, Khan KS, Kilby MD. BJOG. 2010;117(4):382-90.
- **Antenatal ultrasound to predict postnatal renal function in congenital lower urinary tract obstruction: systematic review of test accuracy. (http://www.ncbi.nlm.nih.gov/pubmed/19438489)** Morris RK, Malin GL, Khan KS, Kilby MD. BJOG. 2009;116(10):1290-9.
- **An overview of the literature on congenital lower urinary tract obstruction and introduction to the PLUTO trial: percutaneous shunting in lower urinary tract obstruction (http://www.ncbi.nlm.nih.gov/pubmed/19281572)**. Morris RK, Kilby MD. Aust N Z J Obstet Gynaecol. 2009;49(1):6-10
- **Vesicoamniotic shunting for fetal lower urinary tract obstruction: an overview. (http://www.ncbi.nlm.nih.gov/pubmed/17449853)** Morris RK, Khan KS, Kilby MD. Arch Dis Child Fetal Neonatal Ed. 2007;92(3):F166-8
- **Congenital lower urinary tract obstruction: to shunt or not to shunt? (http://www.ncbi.nlm.nih.gov/pubmed/16336318)** Kilby MD, Daniels JP, Khan K.BJU Int. 2006;97(1):6-8.
- **The PLUTO study the NIHR Health Technology Assessment program (http://www.hta.ac.uk/project/1732.asp)**

For more information

NICE guidance (http://guidance.nice.org.uk/IPG202/PublicInfo/pdf/English)
Antenatal Results and Choices (http://www.arc-uk.org/)

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