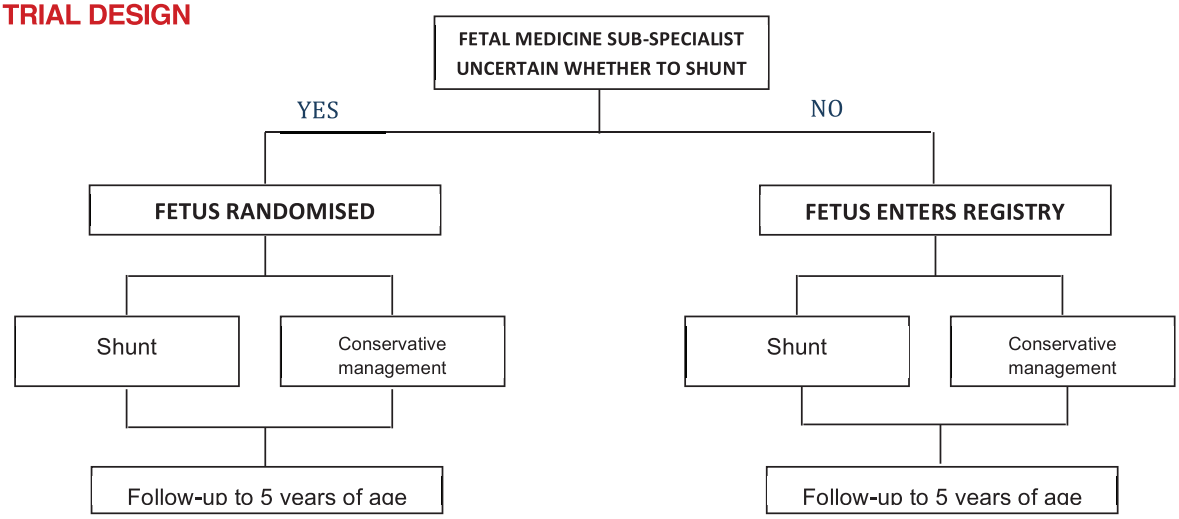
ELIGIBILITY

- Written informed consent given
- Able to understand information provided (use of interpreter may be required)
- Singleton pregnancy for trial (singleton or multiple for registry)
- Evidence of isolated bladder outflow obstruction from ultrasound imaging
- Randomisation is based largely on the "uncertainty principle". That is, if there is a definite indication for or contraindication against shunting then the fetus is not eligible for randomisation. If, however, there is substantial uncertainty as to whether or not shunting is indicated, the fetus is eligible to be randomised.

TRIAL DESIGN



RANDOMISATION

- Obtain mother's consent for randomisation or registration
- Prepare for telephone questions using the randomisation/ registry notepad – all questions will need to be answered
- Go to web page or telephone the randomisation service on 0800 953 0274
- When all the relevant questions on the randomisation/ registry notepad have been answered, a treatment allocation will be given for randomised fetuses and PLUTO reference number will be given.

TREATMENT

- If allocated to shunt, this should be inserted as soon as possible
- The fetus should continue to be monitored every 2-4 weeks and important prognostic data collected on the Prenatal Assessment Form

FOLLOW-UP

- The outcome of the pregnancy and any adverse events are collected spontaneously
- Perinatal and neonatal mortality and renal function are the primary outcome measures
- Follow-up at 12 months, 2 years and 5 years will be undertaken by a paediatric nephrologist/urologist

FOR **RANDOMISATION**

https://www.trials.bham.ac.uk/PLUTO or 0800 953 0274 or FAX 0121 415 9135/6

Also for urgent medical queries. For administrative queries and trial supplies, contact the PLUTO Trial Office, University of Birmingham Clinical Trials Unit, Robert Aitkin Institute, FREEPOST RRKR-JUZR-HZHG, Birmingham B15 2TT UK. Tel: 0121 415 9100