PATIENT INFORMATION SHEET

immediately punctured at delivery of the baby. The back of the bracelet will have the contact number for University College London Hospital if anyone requires any further information.

What are the side effects of FETO?

The centers participating in this study have extensive experience with keyhole surgery in pregnancy and over 200 FETO operations. Each of them has therefore performed several tens FETO procedures by now.

FETO is a minimally invasive operation (also known as keyhole surgery) and does not carry a risk of serious complications for the mother. Minor complications which may occur in more than 1% of cases include localized bleeding or wound infection at the entry site of the instruments.

The most common and important complication of FETO is **early rupture of the membranes with vaginal loss of amniotic fluid**. This problem occurs within three weeks from FETO in about 15% of cases. In some cases the leakage may stop and the pregnancy continues normally. The loss of amniotic fluid may also continue for several weeks until delivery.

In most of cases rupture of the membranes eventually leads to **premature delivery**. This is the reason why overall, FETO increases the risk for preterm delivery; in our hands the average gestation at delivery was 35 and a half weeks.

The FETO balloon will need to be removed at around 34 weeks. If you develop contractions and go into spontaneous labour prior to the balloon being removed, you should immediately present yourself to the delivery suite of the hospital as the balloon will need to be removed immediately after delivery. In the unfortunate event that the baby is delivered and the ballon is not removed in a timely fashion, there is a risk of serious complications to the baby due to lack of oxygen and in case of severe delays this may result in the babyôs death.

The consequences of premature birth depend on the gestation at which this occurs. Normal babies born after 32 weeks usually survive without any long term problems but may require neonatal intensive care for a few days or even weeks. However, in babies with diaphragmatic hernia the added problem of prematurity may increase the risk of death or long term breathing and feeding problems. In that scenario, the survival chances depend on the gestation at delivery and the size of the lung prior to the FETO procedure.

Animal experiments have shown that the balloon does not cause any serious damage to the trachea. This has also been our experience with the majority of babies born after FETO. However, the balloon causes local widening of the trachea, which usually is without any consequences. In some it has led to a cough at deep breathing movements, but most of these were temporary.

If you desire not to participate in the randomized study or to withdraw, we will want to keep in contact with you to know your progress and the outcome. If you do not want us to contact you please let us know and we will respect your wish.

If you wish to withdraw from the study and the fetus has a balloon in the trachea it is important that this is removed by an expert.

What are the possible disadvantages or benefits of taking part?

We do not know at this stage of the trial whether in fetuses with severe diaphragmatic hernia FETO is beneficial or not. The results of this study will help us to manage severe diaphragmatic hernia better in the future. This might either be that the FETO procedure should be recommended or no longer offered, depending on the results of the study.

If during the course of the research new information becomes available about this treatment, we will discuss it with you. In the light of new information, you or your research doctors decide that you should withdraw from the trial this will be arranged.

What if there is a problem?

If you have a concern about any aspect of this study, please contact a member of the research team at the UCLH Fetal Medicine Unit at the contact number mentioned below, who will do their best to answer your questions. By agreeing to take part in the study you do not lose any legal rights. If you remain unhappy and wish to complain formally, you can contact the Patient Advice and Liaison Service (PALS) on Tel: 0203 447 3042, or Email: PALS@uclh.nhs.uk

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential and any information that leaves the hospital will have your name or address removed so that you cannot be recognized from it.

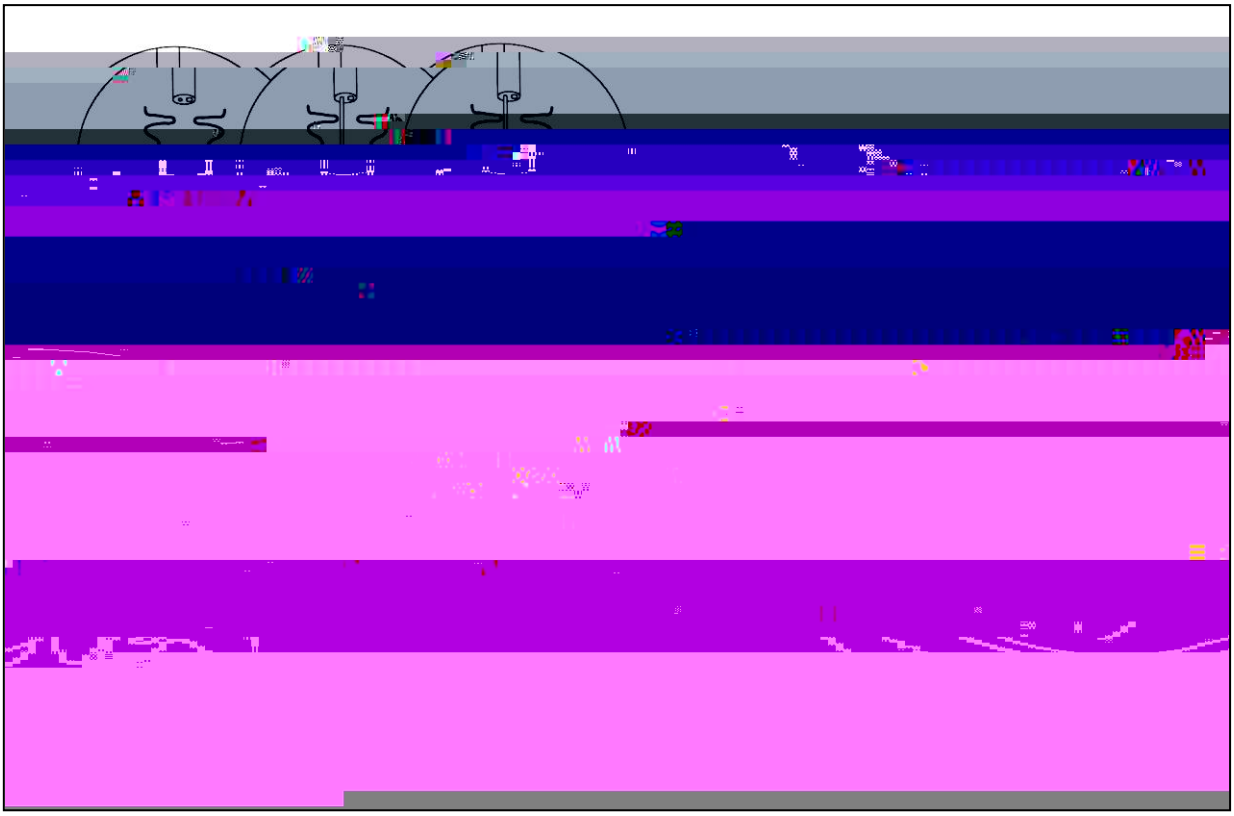
Your GP and your obstetrician will be informed of your participation in the trial unless you have a specific objection.

What will happen to the results of the research study?

Following the analysis of the information we get we will make conclusions and publish the results in scientific journals. Your name or personal details will not be identified on any of these.

Figure:

Illustration of the FETO procedure: through a small cut in the mother's tummy, a miniature telescope is introduced into the mouth of the unborn baby and a balloon is delivered in the trachea. The diagram below shows the introduction of the balloon into the trachea.



Thank you for considering taking part in this research. You will be given a copy of this information leaflet and your consent form to keep.