PATIENT INFORMATION SHEET MODERATE DISEASE

RANDOMIZED TRIAL OF FETOSCOPIC ENDOLUMINAL TRACHEAL OCCLUSION (FETO) VERSUS EXPECTANT MANAGEMENT DURING PREGNANCY IN FETUSES WITH LEFT SIDED AND ISOLATED CONGENITAL DIAPHRAGMATIC HERNIA AND MODERATE PULMONARY HYPOPLASIA

You are being invited to participate in a research study. Before you decide whether or not to take part, it is important for you to understand why we are carrying out this research, and what it

If one can make the lungs grow better before birth, a better outcome would be expected. There is some evidence that in babies with **severe** diaphragmatic hernia the outlook is improved by the placement of a balloon into their wind-pipe (trachea) at about the 26-28th week of pregnancy. The balloon is placed in the fetal trachea by introducing a thin endoscope through the abdomen and womb of the mother, into the amniotic cavity and through the fetal mouth into the trachea. This procedure is called **Fetal Endoscopic Tracheal Occlusion** (FETO). Normally the fetal lungs produce fluid, which escapes through the trachea and mouth into the amniotic cavity. If there is a balloon in the trachea the fluid produced by the lungs remains within the lungs, which increases the pressure within the lungs and provokes their growth. In more than a hundred of these babies, higher than expected survival rates have been observed, and also their need for prolonged oxygen administration was less.

We are inviting you to take part in a **trial** to determine if FETO reduces the chance that your baby will require oxygen therapy for at least one month.

We expect that FETO will provoke lung growth and as such improve their outcome. This is uncertain at this moment as FETO has till now only been offered only to babies with *severe* hypoplasia. In those we have observed a significant lung growth, which was in proportion to the lung size prior to balloon placement. This, together with experimental evidence suggests that also in the moderate group such lung response can be expected. In other words, one could say that when lungs that are larger respond better to balloon placement than small ones. Therefore we have good reasons that the prenatal intervention will make lungs grow, but the question is whether the beneficial effect will not be offset by the side effects of FETO, such as rupture of the membranes and eventually preterm birth.

The benefit of the FETO intervention appears to improve the outcome in cases of severe diaphragmatic hernia but in cases of moderate disease, this intervention has not yet been tried. Therefore, we would like to investigate this in context of a clinical trial as it is likely that as in the cases with severe disease, FETO may also lead to improved outcomes in the moderate disease as well.

Why have I been chosen?

This is because your baby has been diagnosed with an isolated congenital diaphragmatic hernia, which appears to be moderate.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide not to take part in the study your standard of care will not be affected. You will have expectant management as has been offered before for similar cases.

What will happen to me if I take part?

You will be allocated to one or other of two groups, either the expectant management group or the FETO group. A computer selects the group to which you are allocated and the chance of being allocated into each group is equal.

Randomisation

Sometimes we don't know which way of treating patients is best. To find out, we need to compare different treatments. People are put into groups and each group gets a different treatment. The results are compared to see if one is better than the other. To try to make sure the groups are the same to start with, each patient is put into a group *by chance* (which is also called "randomly"). This process is in our study done by a computer, so that nobody can influence this decision. The computer will assign you in one of the two treatments groups and the chance of being allocated into each group is equal.

FETO procedure

If you are allocated into the FETO group the operation will be carried out at 30-32 weeks.
The operation is performed under local anaesthesia.
One hour before the operation you will be given painkillers either orally or through a drip,

prior to the balloon being removed and you are not able to come to University College London Hospital, please report immediately to your local hospital as your consultant obstetrician has been trained to remove the balloon after delivery.

Expectant management

You will not undergo any operation during your pregnancy. For the remainder of pregnancy, the lung growth of your fetus will be monitored by means of ultrasound scan and/or magnetic resonance imaging. We will also monitor any signs of increased fluid around you baby that might need to be drained in order to avoid premature delivery.

Care after birth for both groups

The baby should be delivered in a hospital with facilities for intensive neonatal care and that has expertise in treating babies with diaphragmatic hernia. There is no need for the delivery to be by caesarean section unless there are other obstetric problems.

The main problem for the baby at birth is not the hole in the diaphragm, but the function of the lungs. Immediately after birth the baby will be placed on a ventilator to help with breathing. It will also have a small tube passed from the nose down to the stomach for feeding and to prevent the baby swallowing air, which could compress the lungs even more.

In the first few days after birth it usually becomes obvious whether the lungs have developed sufficiently for the baby to survive or not. Once the condition of the baby on the ventilator is stable an operation is carried out to close the hole in the diaphragm.

The majority of babies that survive will stay in hospital for at least 3-4 weeks but a few cases

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