**STOPPIT-3 Study**

**A Randomised Placebo-Controlled Trial of Antenatal Corticosteroids for Planned Birth in Twins: STOPPIT-3**

**Trial Summary Sheet**

You are being given this information as we would like to invite you to take part in a clinical trial. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully to decide if you wish to take part.

**Why have I been asked to take part?**

You have been asked to take part as you are pregnant with twins.

**What is the purpose of this trial?**

This study aims to find out if the drug antenatal corticosteroids (ACS) given to women with a twin pregnancy prior to a planned birth of twins after 35 weeks of pregnancy reduces breathing difficulties in the twin babies.

Antenatal Corticosteroids (ACS) help to mature babies’ lungs and may reduce breathing difficulties and the need for high levels of respiratory support. They are routinely used in singleton pregnancies which deliver early, but the use of ACS in twin births has not been studied in detail and so it is not clear if they will work in twin pregnancies. Because of the lack of evidence, there is currently no guidance on giving ACS in twin pregnancies, so whether or not women pregnant with twins receive steroids as part of routine care varies depending on their hospital. ACS may also have some unwanted side effects such as lowering babies’ blood sugars, and affecting babies’ growth. We need to be certain about the benefits and risks of giving ACS before all women with twin pregnancy in the UK are offered a course of ACS prior to a planned birth.

Twin pregnancies are monitored more closely as they have a higher risk of complications than a singleton pregnancy, and there is a greater chance of the babies being born before 37 weeks of pregnancy. Twin births account for about 3% of live births but around 15-20% of admissions to the neonatal unit.

Current guidance recommends that twins who share a placenta (monochorionic twins) should be born from 36 weeks of pregnancy if there are no medical problems requiring earlier birth, whilst twins with a placenta each (dichorionic twins) should be born from 37 weeks of pregnancy, as evidence shows this is safer than delivering later on in the pregnancy. Being born slightly early means that twins are at higher risk of admission to neonatal units for support with their breathing, which separates mothers and babies at a crucial time.

We are performing this study in NHS Centres throughout the UK. Women with a twin pregnancy who have a planned birth after 35 weeks of pregnancy are invited to participate in the study. Women who agree to take part in the study will be treated with either ACS or a placebo (dummy drug). These will be administered by injection prior to the planned birth.

We will compare the two groups to see if there are differences in the need for extra healthcare support after birth. If we find that the use of ACS improves health in twin babies, it could be used in the NHS straight away.

We need around 1,550 women to participate in the study to be able to see if ACS work in twins.

**What will happen if I take part?**

An outline of the study is given below. Where possible we will combine any additional visits needed for the trial with your routine antenatal appointments to avoid too many extra appointments However, combining the study visit with routine visits may mean a longer visit overall. Some of the assessments may be carried out virtually before the visit using a remote secure system.

**Consent:** You will be asked if you would like to participate. If you have verbally agreed to participate you will be invited to attend hospital 24 - 120 hours (1-5 days) prior to admission for planned birth, if you are still happy to participate you will be asked to sign the trial consent form.

**Trial data collection:** If you consent to take part some information about you will be collected, including medical, obstetric and current pregnancy history. This information will be entered on to the study database.

**Randomisation:** We don’t always know which treatment is best. To find out, we need to make comparisons between different treatments. We do this by putting people into groups and giving each group a different treatment; the results are then compared to see if one is better. To try to make sure the groups are the same to start with, each participant is put into a group by chance (randomly). This is called randomisation. The results are then compared.

In STOPPIT-3 you will be randomised to one of two groups. There is approximately a 50:50 chance that you will be randomised into either group.

* Corticosteroid Group: Two doses of ACS (Dexamethasone) by intramuscular injection (either to the thigh or buttock)

OR

* Placebo Group: Two doses of visually matching placebo (Sodium Chloride, also known as saline) by intramuscular injection (either to the thigh or buttock)

The trial is a double blind trial, and so neither you nor your doctor/medical team will know which treatment group you are in.

**What are the possible benefit of taking part?**

We don’t know if you and your babies will directly benefit from taking part in this trial. Information we obtain from your participation in the study may help inform on the future healthcare of other patients. Taking part will help create much needed evidence on the use of ACS prior to a planned birth of twins, which will help women and babies in future.

**What are the possible disadvantages of taking part?**

You may be required to spend some extra time at a routine antenatal visit

**Who should I speak to if I am interested in taking part?**

If you are interested in participating in STOPPIT-3 please speak to your midwife/obstetrician. You can also visit our website <https://stoppitstudy.co.uk> to obtain further information.

Additional detailed information about the research will be given further on in your pregnancy. Please tell your midwife, or a member of the clinical care team, if you don’t wish to receive any further information about this trial.

**Do I have to take part?**

No, it is up to you to decide whether or not to take part. If you decide to take part you are still free to withdraw at any time. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

**Thank you for taking the time to read this information leaflet and considering to take part in the study.**