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Version 3, 12th May 2022

C*STEROID

Will you be having a planned caesarean section between 35 and 39^{+6} weeks of pregnancy?

Planned caesarean section

- More than 1 in 10 babies are born by planned caesarean section (CS) before labour starts.
- All ways that women birth have some advantages and some disadvantages for mother and baby.
- Babies born by planned CS are more likely to experience short term breathing problems compared to babies born vaginally or by CS after labour has started.
- If breathing problems occur babies may need to be admitted to the neonatal unit for support with their breathing and closer observation.
- Admission to the neonatal unit means baby is separated from their mother.

Could giving mum corticosteroid injections before planned CS birth at 35^{+0} to 39^{+6} weeks safely reduce the risk of breathing problems for baby?

The C*STEROID study may be suitable for you if you are:

- delivering by planned CS from 35^{+0} to 39^{+6} weeks gestation, and
- pregnant with one baby or twins, and
- able to receive two doses of the study drug between 24 hours and 7 days before your planned birth.

This study may not be suitable if: you have diabetes; you have already received corticosteroid injections during your pregnancy; or your baby is very unwell.

Corticosteroids during pregnancy

Corticosteroids **are routinely given** to mothers when their babies are likely to be born **before 35 weeks**. This improves baby's breathing after birth with little or no risk to the baby's long term health. After 35 weeks we do not have enough good evidence to support their routine use.
We believe that corticosteroids may halve (↓50%) the risk of breathing problems and admission to the neonatal unit for breathing support.

Low blood sugar levels (hypoglycaemia) are common in newborn babies. Around 20-30% of well, full term babies are affected. Up to 50% of babies 'at risk' due to early birth, or who are small or large for their age are affected. Low blood sugars, especially if they are untreated, may affect baby's longer term health.
Generally, only 'at risk' babies are tested.
Corticosteroid use after 35 weeks may alter the chance of a baby having low blood sugar levels after birth. All babies in this study will have their blood sugar levels tested after birth and they will receive treatment if necessary.

What is involved if I take part?

Participation in this study is voluntary. If you are interested in taking part you will be provided a Participant Information Sheet & Consent Form to read. If you agree to take part you will:

- read and sign a consent form.
- receive two injections 24 hours apart in the week before your planned CS. This will be either a corticosteroid (betamethasone) or placebo (saline, 'salt water'). You and your doctors will not know which medication is being given.
- complete questionnaires prior to your planned CS and 6 weeks after birth.

What is involved for baby?

Your baby/babies will have three or four blood sugar tests in the first 12 hours after birth. These require a small prick on baby's heel to collect a few drops of blood. If your baby has a low blood sugar, level this will be discussed with you and they will be treated.

Information about you and your baby/babies will be collected until six weeks after birth. We will ask to contact you from time to time until your child reaches 8 years of age.

Questions?

You may wish to discuss this study with your General Practitioner, a friend, family member or support person.
If you have any questions about this study you can contact us.

This study is supported by your local hospital and has received ethical approval (HDEC ref 20/NTB/166 NZ; HREC/73793/MH-2021 AU). It has been organised by doctors and midwives from The University of Auckland and The University of Melbourne.

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