

# **Summary results**

The CORONIS Trial of caesarean section surgical techniques has found that there is no need at present for doctors to change how they do caesarean section operations. More research is being done to see how the techniques used during the caesarean section affect women in the longer term, particularly when they have another baby.

## Why was the trial needed?

Around the world it is estimated that more than 18 million women undergo a caesarean section every year. It is one of the most commonly performed operations.

A variety of different surgical techniques are used by doctors during caesarean section operations. Many of these had not been carefully compared with each other in clinical trials. We need these trials to know which techniques, if any, give the best outcomes for women and babies.

Because large numbers of women have a caesarean section, if different techniques make even small differences in how women recover from their operation, this could mean improved health for large numbers of women and savings for health services.

The CORONIS Trial was designed to explore five important techniques used during a caesarean section. The trial was funded by the UK Medical Research Council with support from the World Health Organisation.

## What techniques were studied?

CORONIS was a randomised trial, with a complex design. This design has not often been used in medical research, but allows several different techniques to be compared in one trial.

The aspects of the operation that were being investigated were:

- 1. Two different ways of entering the abdomen (tummy) at the start of the caesarean section.
- 2. Two different ways of getting closer to the uterus (womb) after the baby has been delivered to put in stitches.
- 3. Two different methods of closing the uterus (womb) with stitches after the baby had been delivered.
- 4. Two different types of stitch material for closing the uterus (womb).
- 5. Two different ways of leaving the thin covering of the uterus (womb), bladder and abdominal wall (known as the peritoneum) after the uterus (womb) has been closed.

## Where the trial was carried out?

The trial was carried out in; Argentina, Chile, Ghana, Kenya, India, Pakistan and Sudan in collaboration with the National Perinatal Epidemiology Unit Clinical Trials Unit in Oxford. Nineteen hospitals took part.

#### What were the results?

15,935 women who were due to undergo a caesarean section took part in the study between May 2007 and December 2010. The study looked at how well they recovered following the birth.

The techniques in the study were found to make no differences to the number of women who die or have serious infections. However, the use of one kind of stitch (chromic catgut) instead of another (vicryl) was found to reduce the number of blood transfusions that were needed, but the number of women having a blood transfusion was small.

### What do the results mean?

The findings of the CORONIS Trial mean there is no need at present for doctors to change how they do caesarean section operations.

### What do we need to do now?

We still need to find out whether any of the five techniques make a difference to the health of women later in their lives, particularly when they have another baby.

In a small number of pregnancies and births after a caesarean there is a problem with the scar on the uterus (womb). One concern is that there may be a difference in the strength of the scar depending on whether one or two layers of stitches are used to repair the uterus.

We are currently following all women who took part in the CORONIS trial to find out how they are doing. We are contacting them at least 3 years after their CORONIS caesarean section. This follow-up study is funded by the UK Medical Research Council and will produce results in 2016. Knowing about longer term outcomes will help doctors make the best decisions about what surgical approaches to use.

Thank you for participating in the CORONIS Trial. If you would like to talk to someone about the trial or the follow-up study please contact your local CORONIS Regional Trial Office.







