The CORONIS Trial and Follow-up Study

The CORONIS trial of caesarean section surgical techniques was done to find out whether some parts of the caesarean section operation can be improved to reduce the chances of women having pain or infections after surgery. The Follow-up study was done to find out which methods may benefit women in the longer-term. This is particularly important for women who decide to have more children after a Caesarean section.

The study did not find any differences in a range of outcomes, including hernias, infertility, problems with subsequent pregnancies, and symptoms such as pelvic pain or heavy periods. This means that it does not make a difference to the health of women which of the studied methods is used to perform a caesarean.

Why was the follow-up study 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.

The CORONIS Trial compared:

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.

We found no difference between the techniques we studied in the six weeks after the caesarean section. But it is important to find out whether the techniques have any longer term impact. We therefore aimed to follow-up all women who took part in CORONIS for at least three years to see if there were any longer-term effects on the women’s health, particularly in those who had another pregnancy.

The Follow-up Study was funded by the UK Medical Research Council and the UK Department for International Development.

Where the follow-up study 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 was studied?
A detailed medical history was taken from women asking them about their health since their CORONIS caesarean section, paying particular attention to any pregnancies. If women had a condition such as major surgery, or severe complications relating to pregnancy, then their hospital notes were reviewed (with their consent).

Summary for women April 2016
Findings
A total of 13,153 women were followed-up, which is 84% of all the women eligible to be followed-up. Most women were seen between 3 and 4 years after the caesarean section carried out during the CORONIS Trial. Nearly half of the women had at least one subsequent pregnancy, and two-thirds of those had a repeat caesarean section before labour at their next birth.

The study has found that there were no differences between the different surgical techniques used at the CORONIS caesarean section in the clinical outcomes we studied. Overall, severe health problems were uncommon. However, this lack of a difference in clinical outcomes does suggest that doctors’ techniques could change. For example, as there was no difference between the two different types of stitch (suture) material we were comparing, then the least expensive of the two can be safely used. This will help all hospitals afford other treatments rather than wasting money on expensive stitch materials that are not beneficial for women. Similarly, closing the thin covering over the uterus (called the peritoneum) was not helpful in terms of women’s later health, so not doing this part of the operation saves time and uses fewer stitches, which will help the hospitals and the care other women receive. So, although there were no differences seen for women with the different techniques, there are changes in clinical practice which can be made which will help doctors and hospitals.

We want to thank all the women who took part in the CORONIS Trial and Follow-up Study. The information gathered from the thousands of women during CORONIS provides important information to guide doctors about how to do caesarean sections throughout the world.

If you would like to see the full CORONIS Follow-up paper, you can find it using the following link:
http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)00204-X/fulltext