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International study of caesarean section surgical techniques: a randomised fractional factorial trial and follow-up study

Submission date
29/11/2006

Recruitment status
No longer recruiting

Registration date
17/01/2007

Overall study status
Completed

Last Edited
10/05/2016

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
G0500959/G1000469

Study information

Scientific Title

International study of caesarean section surgical techniques: a randomised fractional factorial trial and follow-up study

Acronym
CORONIS

Study objectives
Study hypothesis amended as of 02/08/2007:
The CORONIS Trial aims to evaluate alternative surgical techniques for five specific aspects of caesarean section technique in a large pragmatic randomised controlled trial, to help determine which methods lead to an optimum outcome for women and their infants.

During the trial development phase it was known as the International CAESAR study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Oxford Tropical Research Ethics Committee (OXTREC), 05/03/2007, ref: 013-06
2. Follow-up study: OXTREC,17/11/2010, ref: 013-06

Primary study design
Interventional

Study design
Multicentre factorial randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pregnancy and Childbirth

Interventions
There are five pairs of interventions being tested; however, each participating hospital will only take part in three of these five possible comparisons. The interventions being compared are:
1. Blunt versus sharp abdominal entry
2. Exteriorisation of the uterus versus intra-abdominal repair
3. Single versus double layer closure of the uterus
4. Closure versus non-closure of the peritoneum (pelvic and parietal)
5. Chromic catgut versus Vicryl for uterine closure

Intervention Type
Procedure/Surgery

Primary outcome(s)
Current information as of 29/09/10:
Death or maternal infectious morbidity (one or more of the following: antibiotic use for maternal febrile morbidity during postnatal hospital stay, antibiotic use for endometritis, wound infection or peritonitis) or further operative procedures; or blood transfusion of >1 unit of whole blood or packed cells.

Initial information at time of registration:
Death or serious maternal morbidity (one or more of the following: antibiotic use for maternal febrile morbidity during postnatal hospital stay, antibiotic use for endometritis or wound infection; further operative procedures on the wound; blood transfusion).

Key secondary outcome(s)

All within six weeks of delivery unless stated otherwise:
1. Death
2. Febrile morbidity
3. Endometritis
4. Wound infection treated with antibiotics
5. Operative procedures on wound
6. Pain
7. Blood transfusion
8. Interventions used for severe primary Post-Partum Haemorrhage (PPH)
9. Stillbirth after trial entry
10. Apgar score less than three at five minutes
11. Laceration of baby at time of caesarean section
12. Death of the baby by six weeks of age
13. Other severe maternal morbidity
Health service utilisation:
1. Duration of operation (from incision to closure)
2. Duration of hospital stay post-caesarean section
3. Duration of stay in Intensive Care Unit post-caesarean section
4. Number and duration of re-admissions to hospital within six weeks of the caesarean section

Added as of 13/03/2013: Follow-up Study Outcomes
Womens health and mortality
1. Following the CORONIS birth and before any subsequent pregnancy, any new onset or worsening of:
1.1. pelvic pain
1.2. dysmenorrhoea
1.3. deep dyspareunia
1.4. urinary symptoms of poor stream and/or frequency which did not respond to antibiotics
2. Diagnostic laparoscopy or diagnostic laparotomy (not related to pregnancy)
3. Hysterectomy or tubal/ovarian surgery (not related to pregnancy)
4. Bladder or bowel damage in those women who have had surgery, excluding diagnostic laparoscopy and diagnostic laparotomy (not related to pregnancy).
5. Following the CORONIS birth, any new onset of:
5.1. abdominal hernia
5.2. bowel obstruction
6. Womans death
Reproductive status
7. Number of women with no subsequent pregnancy
7.1. Voluntary infertility
7.2. Involuntary infertility
8. Use of fertility treatments
Subsequent pregnancies
9. Number of women having any subsequent pregnancy and for these women, the following outcomes will be measured:
9.1. Inter-pregnancy interval from the CORONIS birth to the end of the subsequent pregnancy

(regardless of loss or birth)
9.2. Miscarriage of the pregnancy subsequent to the CORONIS birth
9.3. Ectopic pregnancy
9.4. Gestation at delivery (by best estimate) of the first viable pregnancy (gestational age > 24 or >28 weeks depending on country specific definition)
9.5. Stillbirth
9.6. Neonatal death
9.7. Mode of delivery:
9.7.1. Non-instrumental vaginal
9.7.2. Instrumental vaginal
9.7.3. Pre-labour caesarean section
9.7.4. In labour caesarean section
9.8. Other pregnancy complications including: uterine rupture, uterine scar dehiscence, placenta praevia, morbidly adherent placenta, abruption, postpartum haemorrhage requiring transfusion, severe infection within 6 weeks postpartum, hysterectomy up to 6 weeks postpartum, manual removal of placenta,
9.9. Bladder or bowel damage at the time of subsequent caesarean section
CORONIS children morbidity and mortality
10. Death or serious morbidity of the child who was born at the time of CORONIS participation (Although no difference in death is expected, there is likely to be a time difference between sharp and blunt abdominal entry and this may, in theory, lead to more neonatal encephalopathy which may lead to a greater risk of later death).

Completion date
30/06/2015

Eligibility

Key inclusion criteria
Women will be eligible for trial entry if they are undergoing delivery by lower segment caesarean section through a transverse abdominal incision.

Note: women are eligible if they have had no previous, or one previous, caesarean section. Fever in labour is not a contra-indication to trial entry.

Added as of 13/03/2013: All women recruited into the CORONIS Trial and eligible for three year follow-up will have a health assessment conducted by a study assessment doctor.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria

Women will not be eligible for trial entry if there is clear indication for a particular surgical technique or material to be used, that interferes with any of the allocated interventions, e.g. in a previous vertical incision.

Date of first enrolment
01/09/2006

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
United Kingdom

England

Argentina

Chile

Ghana

India

Kenya

Pakistan

Sudan

Study participating centre
University of Oxford
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Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK) (Grant ref: G0500959)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/07/2013		Yes	No
Results article	3-year follow-up results	02/07/2016		Yes	No
Protocol article	protocol	22/10/2007		Yes	No
Protocol article	follow-up protocol	21/11/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes