

Caesarean Section Surgical Techniques - A Randomised Factorial Trial.

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/12/2010	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.npeu.ox.ac.uk/caesar/>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SEO030

Study information

Scientific Title

Acronym

CAESAR

Study objectives

To evaluate alternative surgical techniques for 3 elements of caesarian section operation: single v double layer closure of the uterus; closure v non-closure of the pelvic peritoneum; liberal v restricted use of sub-rectus sheath drain.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Patient information can be found at: http://www.npeu.ox.ac.uk/caesar/caesar_downloads/detailedinfopages.pdf

Health condition(s) or problem(s) studied

Pregnancy and childbirth: Childbirth

Interventions

1. Single vs double layer closure of the uterus
2. Closure vs non-closure of the pelvic peritoneum
3. Liberal vs restricted use of sub-rectus sheath drain

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Antibiotic use for febrile morbidity.

Secondary outcome measures

Endometritis; wound infection; operative procedures on wound; blood transfusion; breastfeeding at hospital discharge; severe or unexpected maternal morbidity; bladder function; cosmetic scar appearance

Overall study start date

01/09/2000

Completion date

01/12/2004

Eligibility

Key inclusion criteria

3500 women undergoing delivery by their first lower segmental caesarean section

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

3500

Key exclusion criteria

Under the age of 16 years

Date of first enrolment

01/09/2000

Date of final enrolment

01/12/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
National Perinatal Epidemiology Unit
Oxford
United Kingdom
OX3 7LF

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
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London
United Kingdom
SW1A 2NL
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dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
<http://www.doh.gov.uk>

Funder(s)

Funder type
Government

Funder Name
NHS Executive South East

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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	01/10/2010		Yes	No