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Caesarean Section Surgical Techniques - A Randomised Factorial Trial.

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/12/2010	Pregnancy and Childbirth	

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
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
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