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Preoperative fasting and postoperative nausea and vomiting after elective caesarean section under spinal anaesthesia: a randomised controlled study

Submission date
30/09/2004

Recruitment status
No longer recruiting

Registration date
30/09/2004

Overall study status
Completed

Last Edited
14/11/2014

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0084125057

Study information

Scientific Title

Study objectives
To compare the effect of two fasting regimens on the incidence of postoperative nausea and vomiting (PONV) after elective lower segment caesarean sections (LSCS) under spinal anaesthesia.

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)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Post-operative nausea and vomiting (PONV)

Interventions
Patients undergoing elective caesarean section will be randomly assigned to either of the following two groups:

Group A: Fasted overnight from 12 midnight
Group B: A light breakfast of two slices of toasts and a cup of tea/coffee will be allowed 4 hours preoperatively

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
08/08/2001

Completion date
01/06/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
40 patients in each group, 80 patients in total

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
08/08/2001

Date of final enrolment
01/06/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Anaesthetics
Hull
United Kingdom
HU3 2JZ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
The North and South Bank Research and Development Consortium (UK)

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