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Which mask for facial oxygen at awake caesarean section?

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/10/2014	Pregnancy and Childbirth	[ ] 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
N0436160509

Study information

Scientific Title

Study objectives
The aim of this study is to determine the efficiency of Hudson and Rebreathing oxygen facial mask in terms of fetal oxygen delivery.

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)
Treatment

Participant information sheet

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

Interventions
Not provided at time of registration

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The oxygen of umbilical vein, and umbilical artery blood result observations are made by an independent observer (which is a routine procedure).

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2004

Completion date
01/05/2005

Eligibility

Key inclusion criteria
Patients requiring elective caesarean section under regional anaesthesia.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Total Target Recruitment: 40

Key exclusion criteria
1. ASA III
2. Failure to attain the level of block (touch to T5)
3. Any intravenous analgesia or anaesthesia are given before the birth of the child

Date of first enrolment
01/12/2004

Date of final enrolment
01/05/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Labour Ward
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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SW1A 2NL
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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