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

Contact name

Dr Gordon Lyons

Contact details

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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 London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

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 summaryNot provided at time of registration