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The effectiveness and acceptability of using a topically applied local anaesthetic to reduce perineal pain during the second stage of labour

Submission date
15/08/2005

Recruitment status
No longer recruiting

Registration date
02/09/2005

Overall study status
Completed

Last Edited
05/07/2018

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

G106/919

Study information

Scientific Title
The effectiveness and acceptability of using a topically applied local anaesthetic to reduce perineal pain during the second stage of labour

Acronym
The Crowning Study

Study objectives
The aim of this study was to rigorously assess the extent to which topically applying a local anaesthetic to the perineum during the second stage of labour reduced the pain experienced by women as their baby is born.
The specific objectives were:
1. To investigate the effectiveness of topically applied local anaesthetic in reducing perineal pain during the second stage of labour
2. To evaluate the impact of this anaesthetic preparation on rates and severity of genital trauma
3. To assess the acceptability of this anaesthetic to women and to the midwives who applied it
4. To identify any risk to the baby of applying an anaesthetic to the perineum immediately before delivery

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 13/08/2007: This trial was approved by the Medicines Control Agency, the local research ethics committee and the participating NHS trust research and development directorate.

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
Childbirth

Interventions
Application of a local anaesthetic spray or placebo spray, applied to the perineum shortly prior to spontaneous vaginal delivery. Each 0.1 ml of active trial solution was formulated to contain: Lidocaine 10 mg, Ethanol 95% 24.1 mg, Poly Ethylene Glycol (PEG 400) 30 mg, H2O to 0.1 ml

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Local anaesthetic

Primary outcome measure
The primary outcome was pain immediately prior to delivery as recorded on the 0-100 Numerical Rating Scale component of the Adapted McGill Pain Questionnaire (Short-Form) and the co-primary outcome the incidence and extent of perineal and other genital tract trauma.

Secondary outcome measures
Delivery:
1. Delivery pain as measured on the remaining components of the AMPQ-SF
2. Maternal satisfaction with delivery analgesia
3. Maternal control and satisfaction with delivery

Neonatal:
1. Levels of lidocaine in cord blood
2. Condition at birth
3. Infant feeding practices

Postnatal:
1. Perineal pain at one week and two months following delivery
2. Perineal problems two months following delivery
3. Maternal feelings two months post delivery as measured on the Edinburgh Postnatal Depression Scale 159 and Maternal Adjustment to Motherhood Scale

Overall study start date
10/03/2003

Completion date
16/05/2004

Eligibility

Key inclusion criteria
The participants comprised nulliparous and parous women who had a live singleton fetus with cephalic presentation at term (more than or equal to 37 weeks gestation) and for whom a spontaneous vaginal delivery was considered imminent.

Participant type(s)

Patient

Age group
Adult

Sex
Female

Target number of participants
170

Key exclusion criteria
During the antenatal period, women falling into certain broad categories were excluded from the trial. These were:
1. Women with a multiple pregnancy
2. Women booked to have a caesarean section, instrumental delivery or episiotomy
3. Women who had previously experienced an adverse reaction to a local anaesthetic
4. Women with insufficient spoken or written English either to provide valid consent or to complete the study questionnaires

Once in labour the following women were also excluded:
a. Women whose pregnancy was less than 37 weeks gestation
b. Women with epidural analgesia
c. Women whose baby had a non-cephalic presentation
d. Women for whom sensitivity dictated that they should not approached to participate in the trial (for example, women whose baby was expected to require immediate intensive neonatal care following delivery) were also not invited to participate. The decision whether or not to recruit an individual woman into the trial was made by the midwife providing care.

Date of first enrolment
10/03/2003

Date of final enrolment
16/05/2004

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Midwifery led Unit
Cardiff
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CF14 4XN

Sponsor information

Organisation
University of Bristol (UK)

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Department of Social Medicine
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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (ref: G106/919) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Wellbeing of Women (ref: NBTF/408) (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	01/09/2002		Yes	No
Results article	results	01/06/2005		Yes	No
Results article	results	15/07/2006		Yes	No