

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

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<b>Registration date</b> 02/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/07/2018	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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, H<sub>2</sub>O 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 be 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

United Kingdom

CF14 4XN

# Sponsor information

## Organisation

University of Bristol (UK)

## Sponsor details

Department of Social Medicine  
University of Bristol  
Whiteladies Road  
Bristol  
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BS8 2PR

## 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?
<a href="#">Results article</a>	results	01/09/2002		Yes	No
<a href="#">Results article</a>	results	01/06/2005		Yes	No
<a href="#">Results article</a>	results	15/07/2006		Yes	No