Randomised controlled trial of restrictive versus routine use of episiotomy for instrumental delivery - a multicentre pilot study

Submission date Recruitment status [] Prospectively registered 19/01/2006 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 20/04/2006 Completed [X] Results [] Individual participant data Last Edited Condition category Pregnancy and Childbirth 07/12/2010

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

Study objectives

Aim to assess the effects of restrictive use of episiotomy compared with routine use during instrumental vaginal delivery

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical approval granted on 12/08/2004, reference number 04/MRE10/29

Study design

Randomised controlled, multicentre pilot study

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

Instrumental vaginal delivery

Interventions

Restrictive versus routine use of episiotomy

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Third or fourth degree perineal tears

Secondary outcome measures

- 1. Mother's perception of pain
- 2. Length of postnatal hospital stay
- 3. Rate of maternal healing complications
- 4. Neonatal trauma

Overall study start date

01/09/2004

Completion date

31/08/2006

Eligibility

Key inclusion criteria

- 1. Primgravidae
- 2. Singleton
- 3. Cephalic presentation
- 4. At term (>37 weeks gestation)
- 5. No contraindications to vaginal delivery

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

200

Key exclusion criteria

- 1. Poor English
- 2. Maternal age <16 years
- 3. Inability to provide informed consent

Date of first enrolment

01/09/2004

Date of final enrolment

31/08/2006

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre Division of Maternal and Child Health Sciences Dundee United Kingdom DD1 9SY

Sponsor information

Organisation

University of Dundee (UK)

Sponsor details

Research and Innovation Services Dundee Scotland United Kingdom DD1 4HN

Sponsor type

University/education

ROR

https://ror.org/03h2bxq36

Funder(s)

Funder type

Charity

Funder Name

Tenovus Scotland T03/23

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2008		Yes	No