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

Submission date
19/01/2006

Recruitment status
No longer recruiting

Registration date
20/04/2006

Overall study status
Completed

Last Edited
07/12/2010

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

T03/23

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 summary

Not 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