

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	<input type="checkbox"/> Prospectively registered
Registration date 20/04/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/12/2010	Condition category 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

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled, multicentre pilot study

Study type(s)

Treatment

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(s)

Third or fourth degree perineal tears

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

Scotland

Study participating centre

Division of Maternal and Child Health Sciences

Dundee

United Kingdom

DD1 9SY

Sponsor information**Organisation**

University of Dundee (UK)

ROR

<https://ror.org/03h2bxq36>

Funder(s)

Funder type

Charity

Funder Name

Tenovus Scotland T03/23

Results and Publications

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