The PErineal Assessment and Repair Longitudinal Study (PEARLS): a national quality improvement initiative to improve the assessment and immediate, short and long term management of perineal trauma

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/08/2007		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
26/03/2008	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
27/09/2013	Pregnancy and Childbirth			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 07/MRE12/2

Study information

Scientific Title

Acronym

PEARLS

Study objectives

That the provision of an evidence based training package and its delivery to practitioners will lead to better outcomes for women following perineal trauma.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Thames Valley Research Ethics Committee, University of Reading. Approved in February 2007.

Study design

Randomised controlled trial using a matched pair cluster design. Maternity units are the unit of randomisation.

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Perineal trauma

Interventions

A paired cluster design trial investigating the intervention of an evidence based, standardised training package delivered to midwives and obstetricians, in the assessment and management of perineal trauma. Twenty-four maternity units have been recruited and matched into 12 pairs. The training intervention will initially commence in one unit in each 'pair' (Group A) with it's matched partner continuing to provide usual care (Group B).

All women in participating units will receive written information antenatally, at around 36 weeks. Following birth, further information about the study will be provided, and informed consent obtained on the Labour Ward, or prior to discharge. Women who participate will receive a pack to take home including a covering letter, 10-12 day questionnaire and a Self Addressed Envelope (SAE). Following receipt of the first questionnaire, the second questionnaire will be sent with an SAE at 3 months.

Main study outcomes will be assessed at three months following cascading of the intervention in Group A units. The intervention will then be cascaded among Group B units.

Please use the following contact details to request a patient information sheet: Sue Tohill/Linda Lucking
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Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

21/03/2013: The previous primary outcome measures were incorrect due to an error at the time of registration. The correct primary outcome measure is as follows:

Experience of perineal pain on daily activity at 10-12 days post birth.

Previous primary outcome measures until 21/03/2013:

Women's perspectives on what they consider important in the quality and experience of their care:

- 1. Infection and antibiotic treatment
- 2. Pain
- 3. Healing
- 4. Continence

Key secondary outcome(s))

21/03/2013: The previous secondary outcome measures were incorrect due to an error at the time of registration. The correct secondary outcome measures are as follows:

- 1. 10 12 days post birth:
- 1.1. severity of perineal pain
- 1.2. need for suture removal
- 1.3. use of pain relief duirng the previous 24 hours
- 1.4. uptake and duration of exclusive breastfeeding
- 1.5. perineal wound infection
- 2. Three months post birth:
- 2.1. Edinburgh Postnatal Depression Scale (EPDS [14])

score of ≥ 13

- 2.2 timing of resumption of intercourse
- 2.3. satisfaction with the perineal repair.
- 2.4. duration of exclusive breastfeeding

Previous secondary outcome measures until 21/03/2013:

- 1. Maternal physical and psychological well-being, assessed by the 10 day and 3 month questionnaires:
- 1.1. Incidence of perineal pain
- 1.2. Use of postpartum analgesia
- 1.3. Perineal wound infection
- 1.4. Uptake and duration of breastfeeding
- 2. Proportion of women who have an Edinburgh Postnatal Depression Scale (EPDS) score of greater than or equal to 13 at 3 months.

Completion date

01/02/2009

Eligibility

Key inclusion criteria

All women who sustain a second degree perineal tear or episiotomy in a participating unit during the study period will be eligible. To avoid problems with selection biases, overall outcomes for the centre will be ascertained using audit data from birth records. All births during a prespecified period will contribute to these analyses.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

- 1. Women under 16 years of age
- 2. Non-English speakers
- 3. Those who have suffered pregnancy loss

Date of first enrolment

01/12/2005

Date of final enrolment

01/02/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre 15 Mansfield Street

London United Kingdom W1G 9NH

Sponsor information

Organisation

Royal College of Midwives (UK)

ROR

https://ror.org/01swa5m73

Funder(s)

Funder type

Charity

Funder Name

Health Foundation - Quality Improvement Initiative (UK)

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	23/09/2013		Yes	No
<u>Protocol article</u>	protocol	25/02/2010		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes