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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	[_] Prospectively registered
20/08/2007	No longer recruiting	[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

Study website
http:www.rcm-pearls.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details provided in the Interventions field to request a patient information sheet.

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:
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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
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

Secondary outcome measures
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.

Overall study start date
01/12/2005

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

Age group
Adult

Sex
Female

Target number of participants
1,000

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
England

United Kingdom

Study participating centre
15 Mansfield Street
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Sponsor information

Organisation
Royal College of Midwives (UK)

Sponsor details
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Sponsor type
University/education

Website
http://www.rcm.org.uk

ROR
https://ror.org/01swa5m73

Funder(s)

Funder type
Charity

Funder Name
Health Foundation - Quality Improvement Initiative (UK)

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?
Protocol article	protocol	25/02/2010		Yes	No
Results article	results	23/09/2013		Yes	No