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Re-stitching of a broken down perineal wound compared to leaving it to heal naturally

Submission date	Recruitment status	[X] Prospectively registered
08/12/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/01/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/10/2017	Pregnancy and Childbirth	

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9098

Study information

Scientific Title
Perineal REpair following Vaginal delivery complicated by an Infected Episiotomy Wound: a feasibility study for a randomised controlled trial

Acronym
PREVIEW

Study hypothesis
Many women will require suturing to facilitate healing of the trauma site. However, practice varies widely between care given and established professionally agreed standards. There is limited data on the prevalence and consequences of perineal wound infection. In addition, there is only a small amount of information relating to the impact that perineal wound infection has on women's well-being during the immediate and long-term post-natal period. Anecdotal evidence suggests the number of women reporting perineal infections and dehiscence in the community is increasing; however, systems to track these complications following hospital discharge are lacking. Given that postpartum management of perineal trauma is a core component of routine maternity care it is vital that a true estimate of the problem is established using standardised definitions of wound infection and at the same time determine best practice when treating dehisced perineal wounds.

Hypotheses:
1. What is the prevalence of perineal wound infection and dehiscence in the UK?
2. What factors at the time of primary repair are most likely to be associated with perineal wound infection and dehiscence prior to discharge to the community?
3. What factors following discharge home are most likely to be associated with perineal wound infection and dehiscence in the community?
4. What are women's experiences of perineal infection and dehiscence and what types of information and support are most likely to benefit their post-natal recovery?
5. What is the best management for perineal wound infection and wound dehiscence?
6. What is the feasibility of conducting a definitive randomised controlled trial (RCT) comparing re-suturing of dehisced perineal wounds versus healing by secondary intention and what are the implications in terms of health benefits and costs?

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Wales Research Ethics Committee, 29/04/2010, ref: 10/WNO03/16

Study design
Computer-randomised controlled feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Condition
Dehisced perineal wounds

Interventions
The participants will be computer randomised into either immediate resuturing of their dehisced perineal wound in comparison to healing by secondary intention. Both groups will have an independent assessment of their perineal wound at 2 weeks and 6 weeks after trial entry. Both groups of participants will be asked to complete a questionnaire at 6 weeks, 3 months and 6 months after trial entry.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Time taken for the dehisced perineal wound to heal, assessed at 2 weeks, 6 weeks, 3 months and 6 months, respectively.

An independent assessment of the primary outcome will be conducted at 2 weeks and 6 weeks using a questionnaire format, the title of the questionnaire being:
'PREVIEW' Independent Perineal Assessment 2 weeks, and
'PREVIEW' Independent Assessment 6 weeks

Mothers will also complete questionnaires at 6 weeks, 3 months and 6 months, respectively, also assessing primary and secondary outcomes, the title of these questionnaires being:
'PREVIEW' Mothers questionnaire 6 weeks
'PREVIEW' Mothers questionnaire 3 months
'PREVIEW' Mothers questionnaire 6 months

Secondary outcome measures
1. Woman's satisfaction with aesthetic results of perineal wound at 6 months post-natal
2. Pain at 6 weeks, 3 and 6 months post-natal
3. Dyspareunia (painful intercourse) at 3 - 6 months
4. Rates of breastfeeding

Mothers will complete questionnaires at 6 weeks, 3 months and 6 months respectively, assessing primary and secondary outcomes, the title of these questionnaires being:
'PREVIEW' Mothers questionnaire 6 weeks
'PREVIEW' Mothers questionnaire 3 months
'PREVIEW' Mothers questionnaire 6 months

Overall study start date
01/04/2009

Overall study end date
01/04/2011

Eligibility

Participant inclusion criteria
1. Women (aged 18 - 40 years) referred to the perineal care clinic at the University Hospital of North Staffordshire
2. Dehisced perineal wound (spontaneous second, third or fourth tear or episiotomy)
3. Occurs within two weeks following childbirth

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
Approximately 250 patients

Participant exclusion criteria
1. Women that have not given their written consent to participate in the study
2. Women who have delivered a stillborn infant
3. Women under the age of 16 years
4. Women who cannot speak English or cannot read or write

Recruitment start date
01/04/2009

Recruitment end date
01/04/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital of North Staffordshire NHS Trust
Staffordshire
United Kingdom
ST4 6QG

Sponsor information

Organisation
University Hospital of North Staffordshire NHS Trust (UK)

Sponsor details
c/o Darren Clement
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Sponsor type
Hospital/treatment centre

Website
http://www.uhns.nhs.uk/

Funder(s)

Funder type
Charity

Funder Name

Smith and Nephew Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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	24/07/2012		Yes	No
Results article	nested qualitative study results	10/02/2017		Yes	No
Results article	results	10/02/2017		Yes	No