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Vaginal preparation at caesarean section

Submission date	Recruitment status	[X] Prospectively registered
10/07/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/08/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/07/2019	Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims
Postpartum infections are bacterial infections of the female reproductive system after childbirth. Post-partum infection is a significant global problem and with increasing antimicrobial resistance there is concern that without action, common procedures such as caesarean section will carry significant risks. Strategies are therefore needed to reduce this risk. The aim is to perform a small study to prepare for a larger study that will compare vaginal cleansing with chlorhexidine gluconate versus the standard practice of no vaginal cleansing immediately before caesarean section, to see whether it reduces post-partum endometritis and sepsis. There are a number of difficulties in performing a study with pregnant women undergoing caesarean section, particularly in an emergency procedure where there is a short interval between decision and delivery. Also, the follow-up of women after caesarean section is unlike other surgical procedures, as mothers are discharged from obstetric care quickly with no routine follow-up after the operation. They are motivated to recover and care for their baby. It is therefore necessary to perform this study to assess both the ability to recruit women and adequately follow them up.

Who can participate?
Women aged 16 and over who are over 24 weeks pregnant and having an elective or emergency caesarean section

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the vaginal cleansing before their caesarean section. This involves an antiseptic solution swab of chlorhexidine gluconate applied to the vagina before the caesarean section. Those in the second group do not receive any vaginal cleansing. Participants are followed up with phone interviews 14 and 30 days later to assess if they developed any post-natal infections and their medical records are checked.

What are the possible benefits and risks of participating?
There are no direct benefits or risks of participating.

Where is the study run from?
1. Birmingham Women's Hospital (UK)
2. Birmingham Heartlands Hospital (UK)
3. Shrewsbury and Telford Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2017 to August 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
34861

Study information

Scientific Title
Vaginal Preparation at caesarean section to Reduce Endometritis and Prevent Sepsis – a feasibility study of chlorhexidine gluconate

Acronym
PREPS

Study objectives
The aim of this study is to perform a feasibility study for a larger multi-centre randomised controlled trial (RCT) comparing vaginal cleansing with chlorhexidine gluconate versus standard practice of no vaginal cleansing immediately before cesarean to reduce post-partum endometritis and sepsis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - City & East Research Ethics Committee, 12/06/2017, ref: 17/LO/0874

Study design
Randomised; Interventional; Design type: Prevention, Drug

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

Health condition(s) or problem(s) studied
Specialty: Reproductive health and childbirth, Primary sub-specialty: General Obstetrics/ Midwifery; UKCRC code/ Disease: Reproductive Health and Childbirth/ Infections specific to the perinatal period

Interventions
Participants are randomly allocated to one of two groups:
1. Those in the first group receive the vaginal cleansing before their cesarean section (CS). This involves an antiseptic solution swab of 0.05% chlorhexidine gluconate applied to the vagina before the CS.
2. Those in the second group do not receive any vaginal cleansing.
Participants are followed up with postnatal phone interviews at days 14 and 30 to assess if they developed any post-natal infections and a check of their medical records will be performed.

Intervention Type
Other

Primary outcome measure
This is a feasibility randomised controlled trial so the outcomes relate to the ability to run this as a full randomised controlled trial. The decision to continue to a full trial will be decided by pre-defined stop-go criteria based on the following outcomes:
1. The proportion of eligible women recruited into the study
2. The proportion of women receiving the allocated intervention
3. The proportion of women who successfully complete the planned follow up process for both the 14 and 30 day telephone interview
4. Withdrawal from the study (defined as a participant requesting that no further data is to be collected from the participant)

The following predicted primary outcome for the full RCT will be collected to inform the sample size of the study and to test data collection methods for the full RCT:
1. Development of endometritis within 30 days after randomisation. Endometritis will be defined as per the definitions set out by the US Centre for Disease Control and Prevention (Centre for Disease Control and Prevention 2017). Obtained through a telephone interview with the woman at 14 and 30 days and a check of the medical records at 6 weeks post natal.

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
18/05/2017

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Women greater than or equal to 34 weeks pregnant having an elective or emergency CS, regardless of indication
2. Women aged 16 years and over
3. Women carrying singletons and all higher order multiples

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Female

Target number of participants
Planned Sample Size: 250; UK Sample Size: 250

Key exclusion criteria
1. Any women with a known allergy to chlorhexidine gluconate or any of its ingredients
2. Unable to give informed consent
3. Unable to receive a telephone interview at 6 weeks post natal
4. Preterm delivery less than 34 weeks
5. Receiving intrapartum antibiotics for GBS prophylaxis or suspected infection in labour

Date of first enrolment
01/10/2017

Date of final enrolment
01/02/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Birmingham Women's Hospital - lead centre
Birmingham Women's and Children's NHS Foundation Trust
Mindelsohn Way
Birmingham
United Kingdom
B15 2TG

Study participating centre
Birmingham Heartlands Hospital
Heart of England NHS Foundation Trust
Bordesley Green
Birmingham
United Kingdom
B9 5SS

Study participating centre
Princess Royal Hospital
The Shrewsbury and Telford NHS Trust
Mytton Oak Road
Shrewsbury
United Kingdom
SY3 8XQ

Sponsor information

Organisation
Birmingham Children's Hospital

Sponsor details
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
Birmingham
England
United Kingdom
B4 6NH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/017k80q27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Results of this trial will be submitted for publication in a peer reviewed journal. The manuscript will be prepared by the chief investigator and authorship will be determined by the trial publication policy. Authors must acknowledge that the trial was performed with the support of BWCFT and NIHR RfPB.

Intention to publish date
31/08/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/06/2018		Yes	No
Results article	qualiative study results	15/07/2019	17/07/2019	Yes	No
HRA research summary			28/06/2023	No	No