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A study comparing wound care techniques following Caesarean section

Submission date
11/04/2016

Recruitment status
No longer recruiting

Registration date
13/04/2016

Overall study status
Completed

Last Edited
02/09/2020

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A caesarean is an operation used to deliver a baby, which can be planned or used as an emergency procedure, when a natural birth is not an option. It involves making a cut in the mother's tummy (abdomen) wall and the womb, through which the baby is taken through. Following a caesarean delivery, there is a risk that the surgical wound can become infected (surgical site infection, SSI). The skin usually acts as a barrier against infection, protecting the blood and internal organs. Following surgery however, bacteria can potentially enter the body through the surgical site, causing an infection. Wound dressings are commonly used to prevent infections of surgical sites in adults however this practice is controversial, as there is not enough evidence showing that wound dressings can help prevent surgical site infections (SSI). The aim of this study is to find out whether leaving the surgical site exposed following a caesarean section leads to a lower amount of SSI's than if the wound is dressed following surgery.

Who can participate?
Pregnant women aged 18 and over who are having a caesarean section

What does the study involve?
Participants are randomly allocated to one of two groups. For those in the first group, the wound from the caesarean section is left uncovered following the procedure. For those in the second group, the wound from the caesarean section is covered after the surgery using a standard wound dressing for 24 hours following surgery, after which it is left uncovered. For participants in both groups, the wounds are examined 24 hours after surgery and when the patient is discharged. Patients are also contacted by telephone 14 and 28 days after surgery in order to find out whether they are satisfied with their treatment and if they have had any infections. The amount of women who develop SSI's in each group is then compared 28 days after surgery.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
University Malaya Medical Centre (Malaysia)

When is the study starting and how long is it expected to run for?
January 2016 to July 2016

Who is funding the study?
University of Malaya (Malaysia)

Who is the main contact?
Professor Tan Pend Chiong

Contact information

Type(s)
Public

Contact name
Prof Tan Peng Chiong

Contact details
Obstetrics and Gynaecology department
University Malaya Medical Centre
Kuala Lumpur
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Caesarean section Wound: Exposed compared to Dressed - A randomised trial

Acronym
C-WED

Study objectives
Superficial surgical site infection rate is lower when the Caesarean section (transverse suprapubic) wound is left exposed compared to dressed at the completion of surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of University Malaya Medical Center, 26/03/2016, ref: 20161-2112

Study design
Prospective 2-arm open label randomised controlled trail

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 below to request a patient information sheet.

Health condition(s) or problem(s) studied
Caesarean section wound care

Interventions
Participants are randomly allocated to one of two groups.

Group 1: The transverse suprapubic Caesarean wound is left exposed after completion of skin closure (wound to be left exposed permanently).

Group 2: The transverse suprapubic Caesarean wound is covered after completion of skin closure with a commercially purchased standard wound dressing (dressing to be removed at 24 hours and subsequently left exposed).

Participants in both groups have their wounds assessed at 24 hours and the time of discharge and are followed up by telephone at 14 and 28 days post-surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Caesarean wound surgical site infection rate is assessed using physical examinations on day 1 and at time of discharge and through telephone interviews on day 14 and 28
2. Patient’s satisfaction with wound management is determined using a visual numerical rating score (VNRS) at hospital discharge

Secondary outcome measures
1. Wound pain is measured using a visual numerical rating score (VNRS) on day 1
2. Pain on the process of wound exposure (i.e. dressing removal compared to exposing wound by lifting clothes in the uncovered wound arm) is measured using a visual numerical rating score

(VNRS) on day 1
3. Need for surgical gauze application to absorb wound exudate or need for dressing (in exposed arm) or dressing change (in dressed arm)
4. Patient preferences for exposed/dressed wound care are determined using a questionnaire specifically designed for the study on day 28
5. Satisfaction with Caesarean wound rated using a 11 point VNRS is measured using telephone interviews on day 14 and 28

Overall study start date
01/01/2016

Completion date
31/07/2017

Eligibility

Key inclusion criteria
1. Age 18 years old or more
2. Undergoing Caesarean section
3. Tested negative for HIV and Hepatitis B in current pregnancy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
334

Total final enrolment
331

Key exclusion criteria
1. Known infectious person particularly if infected with organism transmissible by blood or bodily secretions
2. Category 1 (very urgent) caesarean section
3. Need for compressive wound dressing as per surgeon’s direction
4. Caesarean section requiring midline incision

Date of first enrolment
15/04/2016

Date of final enrolment

30/04/2017

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Jalan Lembah Pantai
Kuala Lumpur
Malaysia
51000

Sponsor information

Organisation
University of Malaya

Sponsor details
Lembah Pantai
Kuala Lumpur
Malaysia
50603

Sponsor type
University/education

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Publication and dissemination plan
Intends to publish findings in an academic research journal

Intention to publish date
01/09/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2020	02/09/2020	Yes	No