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Evaluating abdominal binding using kinesiotape to reduce infection after caesarean section

Submission date
11/03/2022

Recruitment status
No longer recruiting

Registration date
20/03/2022

Overall study status
Completed

Last Edited
08/09/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A caesarean section, or C-section, is an operation to deliver your baby through a cut made in your tummy and womb.
Caesarean delivery related superficial surgical site infection (SSI) rate ranges from 3% to 15% worldwide. SSI after cesarean section is associated with increased maternal illness, prolonged hospital stay, and increased medical costs. The aim is to evaluate abdominal binding using kinesiotape (elastic therapeutic tape) against micropore tape in reducing post Caesarean section SSI.

Who can participate?
Women scheduled for Caesarean section (planned and unplanned) in UMMC

What does the study involve?
The study involves using either kinesiotape or micropore tape (allocated randomly) as abdominal binding in patients post caesarean section and the wound will be assessed by clinical assessment (using the Center for Disease Control (USA) [CDC] SSI criteria) up to hospital discharge and further by phone-based questionnaire on day 15 and day 30.

What are the possible benefits and risks of participating?
Participants should not expect any benefit as it is not known whether the abdominal binding using kinesiotape is helpful in preventing infection of Caesarean wound. There are no expected serious drawbacks anticipated. If, at any time, participant finds it troublesome, she may request to change or remove the tape.

Where is the study run from?
Department of Obstetrics and Gynecology, UMMC (Malaysia)

When is the study starting and how long is it expected to run for?
January 2022 to March 2023

Who is funding the study?
Department of Obstetrics and Gynecology, UMMC (Malaysia)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MREC ID 2021113-10747

Study information

Scientific Title
Effectiveness of abdominal binding using kinesiotape on caesarean surgical site infection

Study objectives
Abdominal binding will benefit obese women by lifting up the abdominal skin fold at the incision site and disrupting a favourable environment for SSI.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/02/2022, Medical Research Ethics Committee University of Malaya Medical Centre (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60379493209/2251; iresearch@ummc.edu.my), ref: 2021113-10747

Study design
Single centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Reducing rate of caesarean wound infection

Interventions
Participants will be randomised in the operating theatre during surgery after closure of the skin by opening the lowest number remaining, sealed and opaque envelope. The envelopes will be kept in a known location within obstetric operation theatres in a box with numbered envelopes arranged in sequence. Opened/unsealed envelopes will be discarded. The random allocation sequence will be generated by an investigator with no clinical involvement in the study. Blinding is not possible due to the nature of the intervention.
After skin closure during Caesarean section and after vaginal cleansing, the abdominal binding will be applied according to randomization (either use Kinesiotape or sham (micropore) tape). Participants are to remove abdominal binding tape and stop using abdominal binding on day 3 after Caesarean delivery.

Intervention Type
Procedure/Surgery

Primary outcome measure
Cumulative SSI rates to day 30 after Caesarean delivery, by clinical assessment (using the Center for Disease Control (USA) [CDC] SSI criteria) up to hospital discharge and further by phone-based questionnaire on day 15 and day 30.

Secondary outcome measures
1. Patient's satisfaction with abdominal binding using visual numerical rating scale (VNRS) at day 15 and day 30
2. Pain score on mobilisation using visual numerical rating scale (VNRS) at day 1, 15 and 30

Overall study start date
01/01/2022

Completion date
14/03/2023

Eligibility

Key inclusion criteria
1. Age 18 years and above
2. Scheduled for caesarean section (planned or unplanned)
3. BMI ≥27.5 kg/m²
4. Access to telephone

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
870

Key exclusion criteria
1. Preexisting abdominal skin infection
2. Hypersensitivity to abdominal kinesiotape or micropore
3. Midline skin incision
4. Category 1 (emergent) Caesarean section

Date of first enrolment
09/04/2022

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
Malaysia

Study participating centre
University of Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
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Sponsor information

Organisation
University Malaya Medical Centre

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Sponsor type
Hospital/treatment centre

Website
http://www.ummc.edu.my/#

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Obstetrics and Gynecology, UMMC

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
14/03/2024

Individual participant data (IPD) sharing plan
The 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?
Participant information sheet	version 2	24/01/2022	16/03/2022	No	Yes
Protocol file	version 1	03/11/2021	16/03/2022	No	No