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Comparison of skin healing after keyhole surgery between transcutaneous suture and non-closure techniques

Submission date
12/06/2019

Recruitment status
No longer recruiting

Registration date
26/06/2019

Overall study status
Completed

Last Edited
30/09/2019

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Minimally invasive procedures such as diagnostic or operative laparoscopy has increasingly becoming the initial access of choice with benefits such as improved appearance such as less scarring and less pain than open procedures. More small surgical cuts made abdominally have been used to assist with the surgery, and the cosmetic outcome has become one of the main factors in determining the closure method. There are various techniques available including conventional suture, skin glue or adhesive tape, but it is mainly based on the surgeon's preference and ultimately patients' satisfaction and to date there is no "gold standard" on the skin closure method for laparoscopic port-site wound. This research aim to compare the closure method for small 5mm laparoscopic wound skin closure between conventional suture versus non-closure method where the surgical incision wound is simply covered with simple dressing after the operation. 5mm laparoscopic wound is a small surgical incision where disruption of the tissues is precise, thus if the wound is approximated within 12 to 24h of its creation - healing naturally is likely to occur. To date, no significant evidence showed that small 5mm laparoscopic wound require more layers to be closed. This research will give surgeons information about the most effective surgical technique for the patient particularly in 5mm port-site wound closure in terms of cosmetic outcome, perception of pain, and wound complications.

Who can participate?
Adults between the age of 18 and 60 who attend gynaecology clinic in University Malaya Medical Centre (UMMC).

What does the study involve?
Participants are asked to join this study while they are at gynaecology clinic. Participants included are those planning for laparoscopic surgery with at least two 5mm lateral ports.
We will randomly assign between the lateral 5mm port-site - at least two ports in each patient to be closed either using absorbable suture or non-closure where simple dressing will be applied over the wound. After 24H, the dressing will be removed for wound inspection and assessment as per our current practice. At around day 14 post surgery, participants will be required to provide feedback on the wound appearance, any symptoms or signs of infection – redness,

drainage, and pain perception for each wound. Participants are instructed to come straight to the hospital if developed any symptoms or signs of infection such as fever or wound drainage. Another follow up will be made at around day 90 post surgery for the final wound assessment. Two blinded surgeons will also provide feedback on the wound appearance at around day 14 and day 90 post surgery.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. But there is a possible benefit of experiencing less pain post surgery since no needle is required from the non-closure method and will also reduce the risk of needle stick injury to the surgeon. The material cost is cheaper compared to suture and operating time will be reduced by implementing the non-closure method therefore the results of this study may help many surgeons in the future to provide the optimal and cost effective care for their patients.

Where is the study run from?
The 5kin_tech is being run by the University of Malaya and takes place in UMMC - gynaecology department.

When is the study starting and how long is it expected to run for?
July 2018 to November 2019

Who is funding the study?
University Malaya Medical Centre - Obstetrics & Gynaecology Department.

Who is the main contact?
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Additional identifiers

Protocol serial number
NMRR-18-3588-45576

Study information

Scientific Title
A randomised controlled trial of non-closure versus transcutaneous suture in 5mm laparoscopic port-site skin wound

Acronym
5kin_tech

Study objectives
H0: 5mm laparoscopic wounds closed with suture or non-closure method will have no significant difference in terms of the cosmetic outcome at 90 days.
H1: There will be different rates of complication and cosmetic outcome indicating superiority of one material over the other.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/12/2018, Medical Research Ethics Committee - University of Malaya Medical Centre (Pusat Perkhidmatan Penyelidikan (PPP), Tingkat 2, Institut Pengurusan & Perkhidmatan Penyelidikan (IPPP), University of Malaya, 50603 Kuala Lumpur, Malaysia; 03-79677022 [ext : 2369]; umrec@um.edu.my), ref: MREC ID 2018731-6551, NMRR-ID NMRR-18-3588-45576.

Primary study design
Interventional

Study design

Prospective randomised controlled study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Laparoscopic surgery

Interventions
Current interventions as of 30/09/2019:
Skin closure technique in 5mm Laparoscopic port-site wound - comparing between transcutaneous suture versus non-closure method.

After informed consent was obtained, randomisation was done intraoperatively to assign each 5mm port site with either closure using transcutaneous suture versus non-closure method where the surgical incision wound is simply covered with simple dressing after the operation.

Randomisation was done by means of a blind envelope system prior to surgery which assigned a closure method to the port closest to the right iliac fossa. Subsequent methods of closure for other port site were assigned in a clockwise fashion.

Wound inspection will be done at day 1 postoperatively at the hospital and immediate complications will be documented. Wound complications (infection, dehiscence, erythema, drainage) will be recorded throughout the hospital stay.

Participants will be asked to evaluate the cosmetic appearance of their wounds at 14 days and 90 days according to VNS (Visual analogue scale). Pain will also be reported by means of VNS.

It was not feasible to blind the participants completely, however, outcome assessors will be blinded to the group assignments as they will only monitor the wound at 14 days and 90 days postoperatively where photos of the wound will be taken and evaluated by two blinded surgeons.

During follow up visit at day 14 and day 90, photograph of the wound will be taken under similar lighting and camera setting for evaluation by blinded assessor who will also use VNS (Visual analogue scale).

Previous interventions:
Skin closure technique in 5mm Laparoscopic port-site wound - comparing between transcutaneous suture versus non-closure method.

After informed consent was obtained, randomisation was done intraoperatively to assign each 5mm port site with either closure using transcutaneous suture versus non-closure method where the surgical incision wound is simply covered with simple dressing after the operation.

Randomisation was done by means of a blind envelope system prior to surgery which assigned a closure method to the port closest to the right iliac fossa. Subsequent methods of closure for other port site were assigned in a clockwise fashion.

Wound inspection will be done at day 1 postoperatively at the hospital and immediate complications will be documented. Wound complications (infection, dehiscence, erythema, drainage) will be recorded throughout the hospital stay.

Participants will be asked to evaluate the cosmetic appearance of their wounds at 14 days and 90 days according to VAS (Visual analogue scale). Pain will also be reported by means of VAS.

It was not feasible to blind the participants completely, however, outcome assessors will be blinded to the group assignments as they will only monitor the wound at 14 days and 90 days postoperatively where photos of the wound will be taken and evaluated by two blinded surgeons.

During follow up visit at day 14 and day 90, photograph of the wound will be taken under similar lighting and camera setting for evaluation by blinded assessor who will also use VAS (Visual analogue scale).

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Overall cosmetic appearance at 90 days from the patient and blinded surgeons' point of view

Key secondary outcome(s)
1. Pain recorded at day 14 postoperatively using VNS (updated 30/09/2019, previously: VAS) score
2. Wound infection noted during clinic follow up and reviewing patient notes
3. Complications noted during clinic follow up and reviewing patient notes

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Female
2. Age >18 y, <60 y
3. Planned laparoscopy with at least two lateral 5mm port
4. Available to come for wound assessment at 14 days and 90 days

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Ports with drainage tube
2. Intraoperative enlargement of port sites
3. Diabetes Mellitus

Date of first enrolment
01/03/2019

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
Malaysia

Study participating centre
University of Malaya Medical Centre
Jalan Universiti
Lembah Pantai
Malaysia
50603

Sponsor information

Organisation
Department of Obstetrics & Gynaecology - University of Malaya

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, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

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

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