

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

Submission date 12/06/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/06/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/09/2019	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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.

Study design

Prospective randomised controlled 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 contact details to request a participant information sheet

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.

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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 measure

1. Overall cosmetic appearance at 90 days from the patient and blinded surgeons' point of view

Secondary outcome measures

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

Overall study start date

01/07/2018

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

70

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

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Sponsor information

Organisation

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<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

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/05/2020

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