

Single-incision appendectomy: an equally safe alternative?

Submission date 31/12/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/01/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/01/2024	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Surgeons constantly strive to refine their techniques into smaller and more effective incisions while ensuring the patient is safe and receives the necessary treatment. This study aims to prove that single-incision extracorporeal appendectomy (removal of the appendix) is the same as performing conventional three-port (three incisions) appendectomy. This will provide a foundation for future studies to compare cosmetic outcomes as well as rates of surgical site hernias.

Who can participate?

Patients aged 18 to 80 years diagnosed with acute appendicitis (inflammation of the appendix) at the study site (Mubarak Alkabeer Hospital)

What does the study involve?

The study involves an operation in which an incision through the umbilicus (belly button) will be made, the appendix will be delivered through that incision and excised and the wound will be closed. This will be compared to the traditional minimally invasive method of making three incisions (one above the umbilicus and two others on the left and lower side of the body) and inserting trochars or ports (the device that allows laparoscopic surgical instruments to be used) and proceeding with surgery using that method.

What are the possible benefits and risks of participating?

The additional benefit is a more cosmetic surgery compared to traditional surgery. The possible risk is an increased rate of wound opening, surgical site infection, and possibly pain.

Where is the study run from?

Mubarak Alkabeer Hospital (Kuwait)

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

October 2020 to October 2022

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

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Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

1793/2021

Study information

Scientific Title

Single-incision extra-corporeal appendectomy compared to conventional multi-ports appendectomy: a case-control study

Acronym

SIEA

Study objectives

Single incision tran-sumbilical appendectomy is non-inferior to conventional laparoscopic appendectomy

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 06/09/2021, Ministry of Health Standing Committee for the Coordination of Health and Medical Research in Kuwait (Ministry of Health Kuwait, Sulaibkhat - Jamal Abdel Nasser Street, Kuwait City, PO Box 5 zip code 13001, Kuwait; +965 (0)24878168; hsc.ethicalcommittee@ku.edu.kw), ref: 1793/2021

Study design

Single-center retrospective case-control study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Acute appendicitis

Interventions

Single incision transumbilical extracorporeal appendectomy. The patients were nonrandom and this novel technique was compared to conventional multiport laparoscopic appendectomy.

Intervention Type

Procedure/Surgery

Primary outcome measure

The non-inferiority of the single incision extra-corporeal appendectomy (SIEA) in comparison to conventional three-port appendectomy (CA). This was measured by first taking the baseline characteristics of both groups in terms of:

1. Gender: male or female, in crude numbers, the two groups were compared using the chi-square analysis
2. Age: in crude numbers and the two groups were compared using the T-test analysis
3. Comorbidities: any patient with a comorbidity (diabetes type 1 and 2, hypertension, dyslipidemia, bronchial asthma, pregnancy, miscellaneous) is recorded, the total number of comorbidities present within the demographic would be summed up and the average number of comorbidities would be compared between the two groups as the number of comorbidities present using the chi-square analysis.
4. Symptoms the patients presented with (abdominal pain, nausea, vomiting, anorexia, fever,

diarrhoea, constipation, dysuria) are recorded and calculated in a percentage format to assess the likelihood for symptoms to occur in both groups, calculate the alvorado score for each patient who presented with such symptoms, calculate the average in both groups and compare them using the T-test analysis.

5. Signs: white blood cell count as per the first two digits of the lab format (e.g. 12 instead of 12×10^9), the averages of both groups are compared using the T-test. Duration of symptoms in days, calculation of both averages achieved using the T-test, image positivity whether by ultrasound or CT image are recorded as either image positive or image negative, and the average occurrences in both groups are compared using the chi-square analysis.

Secondary outcome measures

1. Cost analysis, derived from the cost of the disposable instruments as quoted by the companies that the ministries have contracted to provide for the surgery and calculated as an average cost between the two groups
2. Length of stay in days, recorded, averaged, and compared between both groups
3. Operative time in minutes, recorded, averaged and compared between both groups
4. Readmission rates: whether present or absent in each patient over 12 months, averaged and compared between both groups
5. Complications: stump leak, deep space infection, wound infection, wound dehiscence, reoperation over 12 months. Recorded as either present or absent, the rate of which would be added and the average of both groups compared using statistical tests depending on the variable (t-test, Fischer's exact test, etc)

Noninferiority in this study would be defined as the absence of any increase in a negative variable in terms of complication rates, length of stay, cost, operative time of the study group (SIEA) compared to the control group (CA) while demonstrating no demographic difference between the two groups in terms of signs and symptoms.

Overall study start date

01/10/2020

Completion date

01/10/2022

Eligibility

Key inclusion criteria

1. Acute appendicitis
2. Able to sign a consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

200

Total final enrolment

156

Key exclusion criteria

Underage patients who are unable to provide consent

Date of first enrolment

10/09/2021

Date of final enrolment

10/09/2022

Locations

Countries of recruitment

Kuwait

Study participating centre

Mubarak Alkabeer Hospital

Hawalli Governorate \ Jabriya - Block 4, Street 109

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Sponsor information

Organisation

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Sponsor details

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Sponsor type

Government

Website

<https://www.moh.gov.kw/en/Pages/Default.aspx>

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

28/02/2024

Individual participant data (IPD) sharing plan

The data aforementioned in this form will be made available after analysis in the journal article that is planned to be published. The raw data will be kept in a secure location by the investigators since it contains sensitive information pertaining to patient identity.

IPD sharing plan summary

Not expected to be made available