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Single-incision appendectomy: an equally safe alternative?

Submission date	Recruitment status	[ ] Prospectively registered
31/12/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/01/2024	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/01/2024	Digestive System	[ ] 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

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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. ethicalcommitee@ku.edu.kw), ref: 1793/2021

Study design
Single-center retrospective case-control study

Primary study design
Observational

Study type(s)
Treatment

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(s)
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 x 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.

Key secondary outcome(s))
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.

Completion date
01/10/2022

Eligibility

Key inclusion criteria
1. Acute appendicitis
2. Able to sign a consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

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
Kuwait Ministry of Health

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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