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Wrapping of the appendix stump by the omentum reduces pain and speeds recovery after removal of the appendix

Submission date
26/07/2023

Recruitment status
No longer recruiting

Registration date
07/08/2023

Overall study status
Completed

Last Edited
20/02/2024

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Pain control after laparoscopic (keyhole) surgeries is a major concern. Many factors contribute to pain after laparoscopic appendectomy (removal of the appendix). Researchers have devised a method to reduce pain after laparoscopic appendectomy by wrapping the cecum (the beginning of the large intestine) with the appendix stump by the greater omentum (the fatty tissue that drapes over the intestines) during laparoscopic appendectomy. This study aims to investigate the effectiveness of this method.

Who can participate?
Patients aged over 18 years with appendicitis

What does the study involve?
Participants are randomly allocated to laparoscopic appendectomy with omental wrapping or traditional laparoscopic appendectomy. Postoperative pain and analgesics use are measured. The researchers also recorded operation time, time to pass gas, white blood cells count, C-reactive protein (CRP) on second postoperative day, postoperative nausea, frequency of antiemetic medications, and length of hospital stay.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
National Jeddah Hospital (Saudi Arabia)

When is the study starting and how long is it expected to run for?
May 2020 to June 2023

Who is funding the study?
National Jeddah Hospital (Saudi Arabia)

Who is the main contact?
Maged Rihan, m.rihan@njchospital.com

Contact information

Type(s)
Scientific

Contact name
Dr Maged Rihan

ORCID ID
https://orcid.org/0000-0001-9323-9405

Contact details
National Jeddah Hospital
CairoJeddah
Saudi Arabia
21472
+966 (0)596519744
m.rihan@njchospital.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Omental wrapping of the cecum and appendix stump reduces postoperative pain and speeds recovery after laparoscopic appendectomy: a prospective randomized controlled trial

Study objectives
Wrapping the cecum and the appendix stump by the greater omentum at the end of laparoscopic appendectomy, could minimize postoperative pain and speeds recovery for patients after laparoscopic appendectomy.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/04/2020, Jeddah National Hospital Research Ethics Board (Medina Square, PO Box 7697 , Jeddah, 21400, Saudi Arabia; 7675000; jnchospital@jnchospital.com), ref: 20.43

Transposition of the omentum over the injured organ or tissue is a common surgical procedure. It can be done by simple placing and fixation on the desired site. It has been used to circumvent around the sites of the intestinal anastomosis to strengthen it, and to prevent leakage.

Study design
Single-center prospective single-blinded randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute appendicitis

Interventions
Randomization was done using the computational random number generator method. The evaluators for patients and pain were blinded to the details of the appendectomy operation. The traditional and wrapping groups underwent stratification-randomization in a 1:1 ratio.

In all study patients, laparoscopic appendectomy was done. In the second group, at the end of the procedure, mobilization of the distal part of the greater omentum, and placing it over the cecum to cover the appendix stump to act as an insulator between the stump and the parietal peritoneum, using one or two resorbable tacks to fix the lower surface of the omentum to the peritoneal folds or appendices epiploicae of the cecum and not to the cecal wall itself. In the end, the inflation pressure is gradually decreased, while ensuring that the omentum remains within the scope of vision until it is confirmed that it is in the same place until the abdomen is completely emptied and becomes completely adherent to the parietal peritoneum.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Degree of postoperative intraabdominal (visceral) pain intensity evaluated by visual analogue scale (VAS) at the first 24 hours, between 24 and 48 hours, and 48 to 72 hours following the operation
2. Analgesics administration in the form of parenteral nonsteroidal anti-inflammatory drugs (NSAIDs) measured using the mean number of analgesic doses following surgery at the first 24 hours, and after 24 hours following the operation

Key secondary outcome(s))
1. Operation time measured using time in medical records (minutes) at one timepoint
2. Time to pass gas measured using time in medical records (hours) at one timepoint
3. White blood cell count measured using standard laboratory testing (×103/μL count) and preoperative, and24 and48 hours following surgery
4. C-reactive protein (CRP) measured using standard laboratory testing (mg/L) on the second postoperative day
4. Postoperative nausea measured using a numerical rating scale at 24 hours, 24 and48 hours, and 48 and 72 hours following surgery

5. Frequency of antiemetic medications measured using the mean number of doses recorded following surgery at 24 hours, 24 and48 hours, and 48 and 72 hours following surgery
6. Length of hospital stay measured using time in medical records (days) at one timepoint

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Patients aged more than 18 years
2. Diagnosed with acute appendicitis by clinical examination, ultrasonography, or CT scan

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients with complicated appendicitis by perforation or abscess formation
2. Pregnant women
3. Surgical technique was changed (conversion to open laparotomy, or further surgery was done)
4. Intraoperative finding of short omentum
5. Drainage tube was placed
6. Patient could not distinguish between intra-abdominal pain and pain originating from abdominal wounds
7. Patient expressed desire to terminate the study

Date of first enrolment
01/06/2020

Date of final enrolment
30/05/2023

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Jeddah National Hospital
Jeddah
Saudi Arabia
21472

Sponsor information

Organisation
National Jeddah Hospital

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Jeddah Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets analysed during the study will be available upon request from Maged Rihan (magedrihan@hotmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/01/2024	20/02/2024	Yes	No