

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison the effect of stump closure by endoclips vs endoloop on duration of surgery and complications in patients under laparoscopic appendectomy: A randomized clinical trial

Protocol summary

Summary

The aim of this study is the survey of effect of stump closure on duration of surgery and complications by endoclips compared with endoloop in patients under laparoscopic appendectomy in Shariati Hospital. The interventional study was carried out as a prospective randomized clinical trial between 2013 and 2015. 76 qualified patients who were clinically diagnosed with acute appendicitis, after obtaining informed consent, randomly were assigned into 2 groups with 38 individuals in each (Randomization was carried out based on the randomized figures obtained from the Blocked-Randomization computer program), then they underwent laparoscopic appendectomy. The exclusion criteria for this research included: patients who were in pain more than 4 days, finding a mass in the RLQ area in the examination, phlegmon in images or peritonitis symptoms also the patients who underwent surgeries which turned into open laparoscopic due to adhesion and improper anatomic conditions were excluded from the study (did not occur in our study). 3 ports were inserted in both groups, two 10-mm ports and one 5-mm port. The mesoappendix was cut with ligasure in both groups and the appendiceal stump was closed with endoclips in one group and with endoloop in the other group and they underwent laparoscopic appendectomy. The surgery duration was calculated from the time the skin was cut until the time it was closed. The patients were then compared regarding the surgery duration, postsurgical symptoms such as pain, wound infection, and leakage from the appendiceal stump, the hospitalization period, and the need for repeating the surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507096925N4**

Registration date: **2015-07-29, 1394/05/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-29, 1394/05/07

Registrant information

Name

Shirzad Nasiri

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2450

Email address

nasiri@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of stump closure by endoclips vs

endoloop on duration of surgery and complications in patients under laparoscopic appendectomy: A randomized clinical trial	
Public title	Comparison the effect of stump closure by endoclips vs endoloop on duration of surgery and complications in patients under laparoscopic appendectomy: A randomized clinical trial
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criterion: acute appendicitis. Exclusion criteria: patients who were in pain more than 4 days; finding a mass in the RLQ area in the examination; phlegmon in images or peritonitis symptoms also the patients who underwent surgeries which turned into open laparoscopic due to adhesion and improper anatomic conditions were excluded from the study (did not occur in our study).
Age	From 15 years old to 60 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 76
Randomization (investigator's opinion)	Randomized
Randomization description	
Blinding (investigator's opinion)	Single blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Tehran University of Medical Sciences
Street address	6 th Floor, Central Building of Tehran University of Medical Sciences, Gods St., Keshavarz Ave.
City	Tehran
Postal code	
Approval date	2013-08-18, 1392/05/27
Ethics committee reference number	

1011/130/92/3	
Health conditions studied	
<u>1</u>	
Description of health condition studied	Laparoscopic Appendectomy
ICD-10 code	K35
ICD-10 code description	Acute appendicitis
Primary outcomes	
<u>1</u>	
Description	Operative time
Timepoint	From the time the skin was cut until the time it was closed.
Method of measurement	Record in end of the operation's file
Secondary outcomes	
<u>1</u>	
Description	Surgical site pain
Timepoint	1 day after surgery
Method of measurement	Clinical evaluation and questioning of the patient
<u>2</u>	
Description	Wound infection
Timepoint	1 day after surgery
Method of measurement	Patient's record and Clinical evaluation
<u>3</u>	
Description	Stump leak
Timepoint	1 day after surgery
Method of measurement	Clinical evaluation
<u>4</u>	
Description	Hospital stay
Timepoint	Until the day of discharge from the hospital
Method of measurement	Patient's record

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Description

Technical complications

Timepoint

Operation day

Method of measurement

Patient's record

Intervention groups

1

Description

Endoloop group: 3 ports were inserted in this group, two 10-mm ports and one 5-mm port. The mesoappendix was cut with ligasure and the appendiceal stump was closed with endoloop and they underwent laparoscopic appendectomy.

Category

Treatment - Surgery

2

Description

Endoclips group: 3 ports were inserted in this group, two 10-mm ports and one 5-mm port. The mesoappendix was cut with ligasure and the appendiceal stump was closed with endoclips and they underwent laparoscopic appendectomy.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital, General Surgery Ward

Full name of responsible person

Dr. Shirzad Nasiri

Street address

General Surgery Ward, Shariati Hospital, North Kargar St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research of Tehran Univesity of Medical Sciences

Full name of responsible person

Office of Research & Technology Management

Street address

6th. floor, Central Organization of Tehran University of Medical Sciences, Quds St.,

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellor for Research of Tehran Univesity of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shirzad Nasiri

Position

Assistant Professor of General Surgery

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Shirzad Nasiri

Position

Assistant Professor of General Surgery

Other areas of specialty/work**Street address**

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City

Tehran

Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty