Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of treatment with Negative Pressure on Wound Infection and Healing following open cholecystectomy

Protocol summary

Summary

Surgical wound infection after cholecystectomy is one of the most common complications that increase morbidity and hospital costs. Wound infection control, using modern methods of wound healing, can reduce these complications. Negative-pressure wound therapy (NPWT) is a therapeutic technique using a vacuum dressing to promote healing in acute or chronic wounds and Excess fluid, debris and wound edema are removed. (1) Main Objectives: The aim of the present study is to investigate the effect of NPWT on the healing rate of acute infection following cholecystectomy. (2) Design: In this clinical trial study, 240 patients who underwent Cholecystectomy where divided into two groups based on a randomized block model. Cases of surgical wounds treated with NPWT, and control wounds were treated with classical treatment methods. (3) Setting and conduct: In control group after fascia repair, skin sutured and hydrofilm dressing was done alone.But In case group after fascia and before skin repair,an orang nelaton was put in this space and dressing was done.This nelaton connected to hemovac drain with -60 mmHg pressure. Patients in two group in duration 5 days after surgery was evaluate for wound hematoma, fascia dehiscence, wound infection and healing by clinical and labratory findings. (4-a) inclusion criteria:patients with acute cholecystitis operated under open procedure. (4-b) exclusion criteria:age up to70; anemia; hypoxemia; diabetes mellitus; uremia; malnutrition; coagolopathy; recent vascular events ; CVD; COPD; recent pneumonia; gangrenous or emphysematous cholecystitis; gall bladder empyema; BMI up to35; vitamineA ,C ; steroid consumption; chemotherapy; operation period up to2.5 hour; bulky subcutaneous tissue. (5) Intervention: In case group negative wound pressure therapy with hemovac drain was done. In control group hydrofilm dressing was done daily alone. (6) Main outcome measures: Surgical site wound infection, wound healing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202159015N1**
Registration date: **2012-10-25, 1391/08/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-10-25, 1391/08/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

Budget Of Vice Chancellery For Research And Education, Arak University Of Medical Sciences

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of treatment with Negative Pressure on Wound Infection and Healing following open cholecystectomy

Public title
Negative Pressure Effect on Wound Healing

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: patients with acute cholecystitis operated under open procedure. Exclusion criteria: age up to70; anemia; hypoxemia; diabetes mellitus; uremia; malnutrition; coagolopathy; recent vascular events ; CVD; COPD; recent pneumonia; gangrenous or emphysematous cholecystitis; gall bladder empyema; BMI up to35; vitamineA ,C ; steroid consumption; chemotherapy; operation period up to2.5 hour; bulky subcutaneous tissue.

Age
To **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **240**

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

1

Registry name
nil

Secondary trial Id
nil

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Of Vice Chancellery For Research And Education, Arak University Of Medical Sciences

Street address
Post Box: 1884, Vice Chancellery Of Research And Education, Pardis Site Of University Of Medical Sciences, Basij Sq, Arak

City
Arak

Postal code
38481-76941

Approval date
2011-08-17, 1390/05/26

Ethics committee reference number
90-112-1

Health conditions studied

1

Description of health condition studied
Surgical Site Infection and Wound Healing

ICD-10 code
L08.9

ICD-10 code description
Local infection of skin and subcutaneous tissue, unspecified

Primary outcomes

1

Description
wound infection

Timepoint
5 days after intervention

Method of measurement
clinical findings and wound culture

2

Description
wound healing

Timepoint
5 days after intervention

Method of measurement
pathological servey of wound biopsy

Secondary outcomes

1

Description
wound hematoma

Timepoint
5 days after intervention

Method of measurement
bedside clinical findings

2

Description
fascial dehiscence

Timepoint
5 days after intervention

Method of measurement
bedside clinical findings and sonogeraphy

Intervention groups

1

Description
In case group a orange nelaton was put at the space superior to fascia and inferior to skin and was connected to hemovac drain suction with -60 mmhg negative pressure.skin sutured interrupted and hydrofilm dressing was done.
Category
Prevention

2

Description
In control group skin repaired with nylon 2-0 interrupted suture and hydrofilm dressing was changed daily.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Valieasr Hospital, Arak
Full name of responsible person
Dr. Mohsen Norooz Olyaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellery For Research And Education, Arak University 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

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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