

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 orange net was put in this space and dressing was done. This net was connected to hemovac drain with -60 mmHg pressure. Patients in two groups in duration 5 days after surgery were evaluated for wound hematoma, fascia dehiscence, wound infection and healing by clinical and laboratory findings. (4-a) inclusion criteria: patients with acute cholecystitis operated under open procedure. (4-b) exclusion criteria: age up to 70; anemia; hypoxemia; diabetes mellitus; uremia; malnutrition; coagulopathy; recent vascular events; CVD; COPD; recent pneumonia; gangrenous or emphysematous cholecystitis; gall bladder empyema; BMI up to 35; vitamin A, C; steroid consumption; chemotherapy; operation period up to 2.5 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

Name

Mohsen Norooz Olyaei

Name of organization / entity

Arak University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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dr.maliyae@arakmu.ac.ir

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 to 70; anemia; hypoxemia; diabetes mellitus; uremia; malnutrition; coagulopathy; recent vascular events ; CVD; COPD; recent pneumonia; gangrenous or emphysematous cholecystitis; gall bladder empyema; BMI up to 35; vitamin A, C ; steroid consumption; chemotherapy; operation period up to 2.5 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 survey 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 sonography

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

Street address

Surgery Department, Valieasr Hospital, Valieasr Sq, Arak

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Dr.Hekmatpoo

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

City

Arak

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

Contact

Name of organization / entity

Arak University Of Medical Sciences

Full name of responsible person

Dr .Gholamreza Noori

Position

Thorax Surgeon, Assistant Professor

Other areas of specialty/work

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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