

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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 netlon was put in this space and dressing was done. This netlon 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 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

+98 86 1312 1006

##### Email address

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

Arak

## 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

##### Street address

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

##### Street address

Surgery Department, Valieasr Hospital, Valieasr Sq, Arak

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38149-5-7558

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Noori51@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Position

Thorax Surgeon, Assistant Professor

##### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Resident of General Surgery

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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*