

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### Effect of thyme essential oil on control of pilonidal sinus ulcer infection after surgery

#### Protocol summary

##### Study aim

Effect of thyme essential oil on control of pilonidal sinus ulcer infection after surgery

##### Design

This study is a research project in which a medicinal herb "Thyme" available in the herbal remedies will be used to complete the treatment of patients with pilonidal sinus ulcer after surgery. Patients will then be placed on the wound, in addition to practicing the instructions of the physician and taking the prescribed medications, the soluble thyme essential oil will be placed. The use of herbal medicines and essential oils has long been traditionally used and the benefits of it are now of great interest to researchers. Previously, by the same group of researchers, the same thing has been done on a laboratory mouse and there are significant therapeutic effects observed.

##### Settings and conduct

Clinic and Surgery Department of Vali-e-Asr Hospital and Amiral-Momenin Hospital

##### Participants/Inclusion and exclusion criteria

age 14-60 years, patients of both sexes, referrals, preferably within the first 24 hours after surgery, and completion of informed consent form  
Exit criteria: underlying diseases, burns, open and associated bleeding ulcers

##### Intervention groups

The study was not blinded and patients were randomly divided into three groups of 30. A common treatment group includes: normal saline washing and sterile gauze dressing, and the second group, in addition to the usual treatment of silver sulfadiazine ointment, and the third group, in addition to the usual treatment, receive herbal treatment.

##### Main outcome variables

Evaluation and comparing the size of the wound between three groups

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161017030336N4**

Registration date: **2018-12-10, 1397/09/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-05-04, 1400/02/14**

Update count: **2**

##### Registration date

2018-12-10, 1397/09/19

##### Registrant information

##### Name

Ghasem Habibi

##### Name of organization / entity

Islamic azad university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3367 3208

##### Email address

dr.habibi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-24, 1397/06/02

##### Expected recruitment end date

2019-08-24, 1398/06/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Effect of thyme essential oil on control of pilonidal sinus ulcer infection after surgery

**Public title**

Effect of thyme essential oil on control of pilonidal sinus ulcer infection after surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

The patient has a stitched sore Hospitalized or non-hospitalized Age between 14 and 60 years Patients of both sexes Referral preferably in the first 24 hours after surgery Completion of informed consent form

**Exclusion criteria:**

Underlying diseases (diabetes, hypoxic and ...) Burns Open wounds bleeding

**Age**

From **14 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization, so that the patients included in the study are all divided into two equal groups. One of the groups is considered as the treatment group and the other group is considered.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

**Street address**

Basidj Bridge, Sadasht.

**City**

Arak

**Province**

Markazi

**Postal code**

3819693345

**Approval date**

2018-01-02, 1396/10/12

**Ethics committee reference number**

IR.ARAKMU.REC.1396.277

**Health conditions studied****1****Description of health condition studied**

Complications of surgical wound

**ICD-10 code**

T81

**ICD-10 code description**

Complications of procedures, not elsewhere classified

**2****Description of health condition studied**

Complications of surgical wound

**ICD-10 code**

T81.4

**ICD-10 code description**

Infection following a procedure

**Primary outcomes****1****Description**

Wound surface

**Timepoint**

In the first 24 hours after surgery to one month

**Method of measurement**

Patients' wounds are followed for two weeks and at the end of every three days to one month, the wounds of patients are evaluated.

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Washing with normal saline, spraying diluted thyme essential oil spray on the wound, then sterilized gas impregnated with diluted essential oil on the wound and closed with the band. This is done 1-2 times a day, depending on the patient's condition.

**Category**

Treatment - Drugs

**2****Description**

Control group: Normal saline and sterile gauze dressing. Then the sterilized sterilized gas with normal saline is

laid on the wound and closed with the band. This is done 1-2 times a day, depending on the patient's condition.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Hospital of Vali-e Asr Arak

**Full name of responsible person**

Dr. Mohammad Arjomandzadegan

**Street address**

Basij

**City**

Arak

**Province**

Markazi

**Postal code**

3819693345

**Phone**

+98 86 3417 3505

**Fax**

+98 86 3417 3505

**Email**

mmatinam81@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Arjomandzadegan

**Street address**

Basij

**City**

Arak

**Province**

Markazi

**Postal code**

3819693345

**Phone**

+98 86 3417 3505

**Email**

mmatinam81@yahoo.com

**Grant name****Grant code / Reference number**

2977

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

Yes

**Title of funding source**

Arak University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Ghasem Habibi

**Position**

Research Assistant

**Latest degree**

Bachelor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Pardis of Arak University of Medical Sciences,  
Sardasht, Basidj Bridge, Arak, IR. IRAN

**City**

Arak

**Province**

Markazi

**Postal code**

3819693345

**Phone**

+98 86 3417 3505

**Fax**

+98 86 3417 3505

**Email**

ghasemhabibi.chem@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr.Mohammad Arjomandzadegan

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Microbiology

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**Province**

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+98 86 3417 3505

**Fax**

+98 86 3417 3505

**Email**

mmatinam81@yahoo.com

**Phone**

+98 86 3417 3505

**Fax**

+98 86 3417 3505

**Email**

kebriya.azangoo@gmail.com

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

Arak University of Medical Sciences

**Full name of responsible person**

Kebria Azangoo Araghi

**Position**

Research Assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Nursery

**Street address**

Pardis of Arak University of Medical Sciences,  
Sardasht, Basidj Bidge, Arak, IR. IRAN

**City**

arak

**Province**

Markazi

**Postal code**

3819693345

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable