Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Preparation, characterization and clinical evaluation of the effectiveness of a cotton-based topical product in stopping bleeding from the leech therapy wound

Protocol summary

Study aim
Preparation, characterization and clinical efficacy of cotton-based product in stopping bleeding from leech therapy site

Design
A controlled, parallel-group unblinded randomized phase 3 clinical trial on twenty patients. Blocked randomization

Settings and conduct
40 bleeding wounds from the site of leech therapy in 20 patients referred to centers under the supervision of the university who meet the eligibility criteria will be studied after signing the informed consent. In the intervention group, the wound site will be dressed with a cotton-based composition, and in the control group, this dressing will be done by routine method with sterile gas. In each patient, two wounds will be measured: one wound randomly (by block method) in the intervention group and the other wound in The patient will be placed in the control group.

Participants/Inclusion and exclusion criteria
inclusion criteria: adults with leech therapy indication Conditions of non-entry:clinical or laboratory evidence of coagulation disorder; patients taking drugs affecting coagulation,including antiplatelets, anticoagulants,hemostatic agents such as tranexamic acid,vitamin K, aminocaproic acid and statins,oral contraceptives,herbal medicines containing garlic and ginger;diseases Bleeding, liver cirrhosis,chronic kidney failure,malignancy,skin sensitivity to the product,menstrual periods,facial leech therapy

Intervention groups
Intervention group: dressing with cotton-based topical product Control group: usual dressing

Main outcome variables
Determining the percentage of wounds whose bleeding stops completely after fifteen minutes after local administration of the product.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220625055267N1**
Registration date: **2023-05-18, 1402/02/28**
Registration timing: **prospective**

Last update: **2023-05-18, 1402/02/28**
Update count: **0**

Registration date
2023-05-18, 1402/02/28

Registrant information

Name
Fatemeh Akbari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2025-03-21, 1404/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Preparation, characterization and clinical evaluation of the effectiveness of a cotton-based topical product in stopping bleeding from the leech therapy wound

Public title
Clinical evaluation of the effectiveness of a topical product prepared from cotton in stopping bleeding from the site of leech therapy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adults who have leech therapy indication according to the doctor's opinion.

Exclusion criteria:
Clinical or laboratory evidence of coagulation disorder (ecchymosis, hematoma, petechiae purpura or disorder in PT, PTT, hemoglobin, platelets, glucose, calcium, urea, creatinine) Patients who take drugs that affect coagulability, including anti-platelets (aspirin, clopidogrel (Plavix), dipyridamole (Perzantin), ticlopidine (Ticlid), anticoagulants (warfarin, enoxaparin, rivaroxaban, heparin, streptokinase, etc.), blood thinners such as tranexamic acid, vitamin K, aminocaproic acid and statins and oral contraceptives and herbal anticoagulants such as products containing ginger and garlic بیماران دارای اختلالات خونریزی دهنده مثل ITP، هموفیلی ، سیروز کبدی، نارسایی مزمن کلیه Patients with various malignancies
Menstruating women Leech therapy in the face area Skin sensitivity to the product

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**
In each patient, the number of two bleeding wounds will be measured: one wound will be randomly (blocked) in the intervention group and the other wound will be in the control group.

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: block Randomization Unit: Individual Randomization tool: sealed envelope How to generate random sequence: Manually The patients of two groups are named with codes A and B and the size of the blocks is selected. Number 1 (in the order of ABAB) is selected in the lottery, the first patient will receive treatment A, the second patient will receive treatment B, the third patient will receive treatment A, and the fourth patient will receive treatment B. The fifth patient will be randomly selected from one of the 4 blocks and the type of treatment will be assigned to the fifth to eighth patients according to the block. A selection number has been assigned for each of the 6 blocks and the selection method of each of the blocks will be lottery style.

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 mashhad University of Medical Sciences

Street address
University Street, Mashhad University of Medical Sciences

City
Mashhad

Province
Razavi Khorasan

Postal code
13944-91388

Approval date
2023-04-07, 1402/01/18

Ethics committee reference number
IR.MUMS.REC.1402.018

Health conditions studied

1

Description of health condition studied
Bleeding from the site of leech therapy

ICD-10 code
D69.9

ICD-10 code description
Coagulation defect, unspecifiez, Haemorrhagic condition, unspecified

Primary outcomes

1

Description
The percentage of wounds whose bleeding will be completely stopped after local administration of the product

Timepoint
Fifteen minutes after using the product

Method of measurement
Monitoring bleeding from the site by clinical observation

Secondary outcomes

1

Description
clinical Bleeding from the site of leech therapy after the patient leaves the clinic
Timepoint
After leaving the clinic up to 72 hours after using the product
Method of measurement
Observing bleeding from the wound site

2

Description
Possible side effects caused by the administration of the product within 72 hours after the administration of the product
Timepoint
From the time of leaving the clinic until 72 hours later
Method of measurement
Reporting the complication by the patient

Intervention groups

1

Description
Intervention group: Dressing the site of leech therapy with a topical product based on cotton
Category
Treatment - Other

2

Description
Control group: Dressing the site of leech therapy with routine dressing
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Traditional Medicine Clinic of Imam Reza Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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