Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Study of the effect of adding samen-ista powder in controlling bleeding of superficial scalp injuries in patients referred to the emergency department

Protocol summary

Study aim

Determining the effect of adding samen-ista powder in controlling of bleeding of superficial scalp injuries in patients referred to the emergency department

Design

In a randomized single-blind clinical trial with control and some parallel groups, phase II will be carried out on 90 patients. Randomization will be done through the sealed-envelope method using the Randomaize.com site.

Settings and conduct

After the initial steps to irrigate the wound, the patients will be randomly divided into two groups. Special codes (A, B) will be assigned to the intervention and placebo package so that the participants are unaware of the type of treatment received.

Participants/Inclusion and exclusion criteria

The inclusion criteria are the age of >18 years, informed consent to participate in the study, active bleeding, and consistent vital signs. The exclusion criteria: having underlying coagulation diseases, use of anticoagulants, pregnancy, arterial bleeding, the need for additional treatment / the age of >65 years, injuries with burns (electrical, thermal, chemical burns) or crushes, having active inflammatory lesions, neoplasm, active infectious lesions (bacterial, fungal, viral, or parasitic), recent surgery on the scalp (within two weeks) or hair transplant in the last 3 months, and renal failure (ESRD).

Intervention groups

The intervention group will receive Samen Ista medicine, which is a 4-gram vial. The white powder is first dissolved in 25 CC of distilled water and then poured on the bleeding site within 5 to 10 seconds using a syringe. If the bleeding is not controlled within 90 seconds, the patient will undergo routine bleeding control treatments if necessary.

Main outcome variables

Injury dimensions (1-12 cm), scalp injury location, duration of active bleeding, reperfusion, duration of homeostasis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210703051771N1**
Registration date: **2021-09-12, 1400/06/21**
Registration timing: **prospective**

Last update: **2021-09-12, 1400/06/21**
Update count: **0**

Registration date

2021-09-12, 1400/06/21

Registrant information

Name

Hamideh Feyz Disfani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5253 6229

Email address

kazem3293@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of adding samen-ista powder in controlling bleeding of superficial scalp injuries in patients referred to the emergency department

Public title

Effect of adding samen-ista powder in controlling bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of >18 years Informed consent to participate in the study Active bleeding and consistent vital signs

Exclusion criteria:

Having underlying coagulation diseases Use of anticoagulants Arterial bleeding Need for additional treatment Age of >65 years Injuries with burns (electrical, thermal, chemical burns) or crushes Having active inflammatory lesions Neoplasm Presence of active infectious lesions (bacterial, fungal, viral, or parasitic) Recent surgery on the scalp (within two weeks) or hair transplant in the last 3 months Renal failure (ESRD) Pregnancy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The sealed-envelope method is going to be used to generate a random allocation sequence. In this method, the contents of the envelopes, including random numbers, will be prepared and printed by a research team member using the Randomaize.com site and will be put inside the envelopes. They will be sealed so that their contents will not be visible from the outside. The research aim will then be explained to each person who meets the inclusion criteria, and if desired,/he will sign the informed consent and take an envelope, open it, and enter the intervention or control group based on the content of the envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, participants are blinded to the intervention received based on codes (codes A and B) that people are unaware of the type of intervention received and only researchers are aware of it.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of the Mashhad University of Medical Sciences.

Street address

Shahid Hasheminejad hospital, Abourihan Blvd, Tollab, Mashhad city.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2021-04-27, 1400/02/07

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.107

Health conditions studied

1

Description of health condition studied

Open wound of the unspecified body region.

ICD-10 code

T14.9

ICD-10 code description

Unspecified injury

Primary outcomes

1

Description

Injury dimensions (1-12 cm).

Timepoint

It will be carried out in a 1-day period, the wound will be examined for homeostasis, and the time required for homeostasis will be recorded.

Method of measurement

Measurement of Injury dimensions

2

Description

Scalp injury location

Timepoint

It will be carried out in a 1-day period, the wound will be examined for hemostasis, and the time required for

homeostasis will be recorded.

Method of measurement

Measurement of Injury dimensions

3

Description

Duration of active bleeding

Timepoint

It will be carried out in a 1-day period, the wound will be examined for hemostasis, and the time required for homeostasis will be recorded.

Method of measurement

According to the duration of active bleeding.

4

Description

Re-perfusion

Timepoint

It will be carried out in a 1-day period, the wound will be examined for hemostasis, and the time required for homeostasis will be recorded.

Method of measurement

Re-perfusion

5

Description

Duration of homeostasis

Timepoint

It will be carried out in a 1-day period, the wound will be examined for hemostasis, and the time required for homeostasis will be recorded.

Method of measurement

According to the duration of homeostasis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: The intervention group will receive Samen Ista medicine, which is a 4-gram vial. The white powder is first dissolved in 25 CC of distilled water and then poured on the bleeding site within 5 to 10 seconds using a syringe. If the bleeding is not controlled within 90 seconds, the patient will undergo routine bleeding control treatments if necessary.

Category

Treatment - Drugs

2

Description

Control group: In the control group, besides routine treatments, a vial of distilled water will be poured on the wound as a placebo.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Hasheminejad Hospital

Full name of responsible person

Hamideh Feiz Disfani

Street address

Shahid Hasheminejad hospital, Abourihan Blvd, Tollab, Mashhad city

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Email

feyzh@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamideh Feiz Disfani

Street address

Shahid Hasheminejad hospital, Abourihan Blvd, Tollab, Mashhad city

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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

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamideh Feiz Disfani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamideh Feyz Disfani

Position

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Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Because the researchers follow ethical standards, the information of all the participants will be recorded anonymously, and their informed consent on the publication of the research results will be got to avoid any problems regarding the publication of the study data.

When the data will become available and for how long

Eight to twelve months after the publication of the study results.

To whom data/document is available

The researchers working in scientific centers and academic institutions.

Under which criteria data/document could be used

1- Contributing to continue clinical research in this field 2- Using in systematic reviews 3- Performing more statistical analyzes to improve the reporting accuracy and reduce possible errors

From where data/document is obtainable

Dr. Hamideh Feiz Disfani

What processes are involved for a request to access

data/document

Sending a written request to the project manager and all the researchers involved in the project

Comments