

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The survey of the efficacy of new hemostatic polysaccharide powder to control bleeding in acute traumatic patients

Protocol summary

Study aim

Assessment of the efficiency of polysaccharide homeostasis powder in trauma patients of RAJAEI Hospital

Design

The present study is a single-blinded, stratified randomized controlled clinical trial with two arms in trauma patients over the age of 18 at Shiraz Rajaei Hospital during the year 1400. For 192 samples, the randomization is done with a table of random numbers in three layers (skin, liver, abdomen) and two groups (case and control).

Settings and conduct

At Rajai Trauma Hospital in Shiraz, depending on the size of the wound, 1 to 5 grams of powder is sprayed to the bleeding site (the maximum allowed in a patient is 50 grams). The location of the wound and other information, including the effectiveness of the powder will be recorded. We check blood clot formation after 3 and 5 minutes of spraying. During a check, the spraying is repeated if the powder has been removed. Control group members follow the same powder-free steps using dry gauze and pressure. We count Gauze numbers with at least 50% bloody appearance. In the following days, the wound's surface is evaluated for tissue reactions and possibly powder residues (Also if the wound is reopened). The TBS (Target bleeding site) and Surface Bleeding Severity Scale (SBSS) and the rate of hemostasis are used to report data.

Participants/Inclusion and exclusion criteria

Trauma patients over 18 years of age, with stable clinical conditions and non-infectious wounds, who did not have underlying renal, hepatic, diabetic, or coagulation disorders are included in the study.

Intervention groups

Intervention group: Trauma patients with mild to moderate bleeding wounds that the powder is used to control bleeding according to the instructions. Control group: Similar patients but without the use of control

powder for bleeding

Main outcome variables

Bleeding control time; Bleeding volume; Surgeon satisfaction; The rate of gross tissue reaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121117011491N3**

Registration date: **2021-11-12, 1400/08/21**

Registration timing: **prospective**

Last update: **2021-11-12, 1400/08/21**

Update count: **0**

Registration date

2021-11-12, 1400/08/21

Registrant information

Name

Hamid Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-21, 1400/08/30

Expected recruitment end date

2022-05-20, 1401/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The survey of the efficacy of new hemostatic polysaccharide powder to control bleeding in acute traumatic patients

Public title

Evaluation of the effect of new polysaccharide homeostasis powder in controlling bleeding

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Accepting and signing the informed consent of the patients' legal guardian to allow the use of the powder produced in controlled conditions for the patient
Existence of ulcers with mild to moderate bleeding with stable vital sign Age more than 18 years Liver and Pelvic damage without peritoneal perforation

Exclusion criteria:

Infectious or contaminated wounds with soil or abdominal contents Peritoneal perforation Diabetes Renal or Liver failure Past medical history of Hypersensitivity (Hospitalization or hypotension due to drug anaphylaxis) Past medical history of Autoimmune or Immunodeficiency disease or disorder Severe Malnutrition Hereditary coagulation disorder or severe coagulation disorders that prevent patients from the operation Gall bladder laceration of rupture uncontrolled shock state

AgeFrom **18 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample sizeTarget sample size: **192**

More than 1 sample in each individual

Number of samples in each individual: **2**

Skin, Live, and abdominal laceration may be seen in a patient that each lesion can be nominated as a sample

Randomization (investigator's opinion)

Randomized

Randomization description

The stratified randomization method is used in this study. In order to achieve a balance , blocks with size of 4, 6 and 8 are used. For randomization tools, online sources of random table generation have been used, and the generated tables comply with the following specifications. Here are the specifications used to create this table. Block sizes: 4,6,8 Actual list length: 190 Stratification factors: Site (Liver, Abdomen, Skin) Treatment group: Group A, Group B Allocation

concealment will be used for concealment and will only be revealed when the patient is assigned to a patient group in the operating room. This is done using sealed envelopes that cannot be read from the outside; the envelope will be opened by the operating room in charge at the moment of surgery and the patient group will be identified. It is impossible to guess the group based on the envelope number since envelopes are randomly numbered.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the use of powder and lack of access to similar powders, double-blinding is not possible. Statisticians are unaware of the groups, but surgeons are. It is discussed with all patients that the powder will be used, but they don't know if it has been used. A patient does not notice that the powder was used during anesthesia because the wounds close as well. The analyst will be unaware of the two groups and analyzes will be conducted in two groups without drug specifications.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee School of Medicine - Shiraz University of Medical Sciences

Street address

Setad

City

shiraz

Province

Fars

Postal code

7134814336

Approval date

2021-09-06, 1400/06/15

Ethics committee reference number

IR.SUMS.MED.REC.1400.340

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

bleeding

ICD-10 code

R58

ICD-10 code description

Hemorrhage, not elsewhere classified

Primary outcomes

1

Description

The rate of successful hemostasis

Timepoint

Record of hemostasis status at 3 and 5 minutes since powder spray time

Method of measurement

Recording the amount of residual bleeding based on the Surface Bleeding Severity Scale at 3 and 5 minutes after powder spraying

2

Description

Wound bleeding volume before reaching homeostasis

Timepoint

5 minutes after STARTING THE WOUND EVALUATION

Method of measurement

The number of sterile gauze consumed with more than 50% bleeding

Secondary outcomes

1

Description

Gross tissue reaction

Timepoint

One to three days after powder application as daily record

Method of measurement

Depending on the severity of the tissue reaction, the wound reaction is graded from one to six. Scoring one means there is no obvious tissue reaction, and scoring six means there is necrosis at the wound site. Data entry forms include this scoring system and the registering user check the appropriate grade.

Intervention groups

1

Description

Intervention group: Control bleeding in wounds with moderate or mild bleeding by modified and sterile polysaccharide powder, produced by Knowledge-based Healda Company and Shiraz University of Medical Sciences, with one to 5 grams depending on the size of the wound beside all common methods that are used to control bleeding. The powder may be used one to three times. The powder is biocompatible and biodegradable and is used in trauma patients in operating rooms under sterile conditions.

Category

Treatment - Drugs

2

Description

Control group: Trauma patients with mild to moderate bleeding wounds use gauze and pressure as a common method of bleeding control to control their bleeding. No placebo was used for these patients.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaee Hospital

Full name of responsible person

Hamid Mohammadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Web page address

<http://research.sums.ac.ir/fa/index.html>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

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

Shiraz University of Medical Sciences

Full name of responsible person

Hamid Mohammadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available