

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Effects of bromelain and serrapeptase supplementation on surgical and traumatic wound healing and pain reduction (a double blind randomized controlled trial)

#### Protocol summary

##### Study aim

Determining the effect of oral bromelain and Serrapeptase in reducing pain and size of the wound of surgery or trauma compared to placebo

##### Design

80 participants (no=40 per group) are randomly assigned to intervention and placebo group using random digit table

##### Settings and conduct

This double blinded study will be performed in Hakim medical clinic

##### Participants/Inclusion and exclusion criteria

inclusion criteria: male and non-pregnant woman >18 y, up to 1 week post surgery or trauma, wound size of 1-10cm in 1st visit, willing to participate in the study  
exclusion criteria: HbA1C >10, collagen vascular Dis., autoimmune Dis., infectious of wound due to American Infectious disease society criteria, Using steroidal drugs (exp.: topical and inhale steroidal medication) in 2 months prior to study, using antibiotics in a week prior to study, radiation of wound cite, venous insufficiency or osteomyelitis, renal disorders ((blood urea nitrogen < 21.4 mmol/l, creatinine < 247.5 umol/l), liver failure, MI in 3 months prior to study, drug or alcohol abuse, allergy to bromelain and Serrapeptase

##### Intervention groups

after assessing demographic, clinical and medical history, patients will use bromelain and Serrapeptase cap. BD for 10 days (each cap. contains 250 mg bromelain and 30 mg Serrapeptase)

##### Main outcome variables

Effects of bromelain and serrapeptase supplementation on surgical and traumatic wound healing and pain reduction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140804018677N6**

Registration date: **2021-02-15, 1399/11/27**

Registration timing: **prospective**

Last update: **2021-02-15, 1399/11/27**

Update count: **0**

##### Registration date

2021-02-15, 1399/11/27

##### Registrant information

##### Name

soodeh razeghi Jahromi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6634 8500

##### Email address

razeghi@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-28, 1399/12/10

##### Expected recruitment end date

2021-07-01, 1400/04/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Effects of bromelain and serrapeptase supplementation on surgical and traumatic wound healing and pain reduction (a double blind randomized controlled trial)

### Public title

Effects of bromelain and serrapeptase supplementation on surgical and traumatic wound healing and pain reduction

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Male and non-pregnant female age > 18y Up to 1 week post trauma or surgery Wound size between 1-10 cm tend to use this supplement

#### Exclusion criteria:

Allergy to bromelain and serrapeptase Collagen Vascular or autoimmune Diseases mild-moderate and severe wound according to American infectious disease society criteria Using steroidal drugs in 2 months prior to study (exp. inhaled steroidal drugs for COPD and asthma and topical steroidal medication Using antibiotics in a week prior to study radiation therapy of wound HBA1c > 10 venous insufficiency or osteomyelitis Using immunosuppressant active malignancies Renal disorders ((blood urea nitrogen < 21.4 mmol/l, creatinine < 247.5 umol/l) or liver failure MI in 3 months prior to study Drug or alcohol abuse

### Age

From **18 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### Sample size

Target sample size: **80**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Participants will have equal chance to be assigned to studied groups. We will use random digits table to make random sequence. After determining the first number, we will continue downward and allocate even numbers to cases and odd numbers to placebo. As in small sample sizes, it would be probable that one group be completed earlier, if one group completed earlier, we will allocate the other assigned numbers to other group. A person out of study group will put her figure on one digit of the table with closed eyes and according to assumed agreement will go downward through the table and write the numbers down until completing the sample size in each

group. Code "A" will allocated to even numbers and considered as "intervention group" and code "B" will allocated to odd numbers and considered as "placebo group". At the end we will have the sequence of 80 specific numbers and A&B codes. A person out of study team will put the numbers in sealed packets till the time of sampling

### Blinding (investigator's opinion)

Double blinded

### Blinding description

It is a double blind study. A third person out of study team have the sequence of codes that provide the team with sealed pockets containing allocation code at the time of sampling. The following groups of people involved in the trial: participants, Research team including principle investigator, data collectors, and outcome assessors will be blind.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of research and technology deputy of Shahid beheshti University of medical Sciences

##### Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

##### City

tehran

##### Province

Tehran

##### Postal code

1981619573

#### Approval date

2021-02-08, 1399/11/20

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1399.1031

## Health conditions studied

### 1

#### Description of health condition studied

trauma

#### ICD-10 code

G89.11

#### ICD-10 code description

Acute pain due to trauma

## Primary outcomes

### 1

#### Description

pain of wound (trauma or surgical)

#### Timepoint

Baseline and at the end of the study

#### Method of measurement

VAS (visual analog scale)

### 2

#### Description

size of wound (trauma or surgical)

#### Timepoint

Baseline and at the end of the study

#### Method of measurement

Centimeter

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Eating bromelain/serrapeptase capsules (250 mg bromelain and 30 mg serrapeptase per cap) BD (every 12 hours) for 10 days. Capsules are manufactured in "Dayan Teb Eksir" pharmaceutical company

#### Category

Treatment - Other

### 2

#### Description

Control group: Placebo cap. for 10 days BD (every 12 hours) containing maltodextrine. Capsules are manufactured in "Dayan Teb Eksir" pharmaceutical company

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hakim medical clinic

##### Full name of responsible person

Soodeh Razeghi Jahromi

##### Street address

No. 46, West Arghavan St., Farahzadi Blv., Qods Town

##### City

Tehran

##### Province

Tehran

#### Postal code

1981619573

#### Phone

+98 21 2235 7483

#### Email

soodehrazeghi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research and technology deputy, Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

No. 46, West Arghavan St., Farahzadi Blv., Qods Town

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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

Research and technology deputy, Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Soodeh Razeghi Jahromi

##### Position

Associate professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nutrition

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

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

Shahid Beheshti University of Medical Sciences

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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**

All data would be available to public

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

To all

**Under which criteria data/document could be used**

No other criteria

**From where data/document is obtainable**

Email to soodehrazeghi@gmail.com

**What processes are involved for a request to access data/document**

sending email

**Comments**