Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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
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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
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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 updating data

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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