Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Evaluation of the therapeutic effects of bromelain-based supplement (Anaheal 1200 GDU enteric coated) on ecchymosis, swelling and pain after blepharoplasty in patients over 18 years old versus placebo

Protocol summary

Study aim

Evaluation of the therapeutic effects of bromelain-based supplement (anaheal 1200 GDU enteric coated) on ecchymosis, swelling and pain after blepharoplasty

Design

A randomized double blinded placebo-control phase 3 clinical trial on 50 patients.

Settings and conduct

This study will be conducted on post-blepharoplasty patients over 18 years of age at Saadat Abad Surgery Center. The first group will receive antibiotics, pain relievers, anti-inflammatory medications, and the Anaheal 1200 GDU supplement, which contains bromelain. The second group will receive antibiotics, pain relievers, anti-inflammatory medications, and a placebo containing Avicel. All patients will be provided with an informed consent form to ensure they are fully informed about the study process.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults 18 years and older who have undergone blepharoplasty, are able to complete the consent form, and can follow the study protocol appropriately. Exclusion criteria: patients with allergies to certain foods (pineapple, celery, carrots, fennel), pregnant and lactating women, severe kidney and liver disorders, hemophilia, taking anticoagulants, patients with irregular heartbeat, tachycardia, asthma and other allergies that could interfere with the study.

Intervention groups

In the experimental group, 25 adult post blepharoplasty patients will receive the Anaheal 1200 GDU supplement in addition to standard treatment. In the control group, 25 post blepharoplasty adults will receive a placebo in addition to standard treatment.

Main outcome variables

the rate of ecchymosis, swelling and pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230629058615N5**
Registration date: **2024-09-15, 1403/06/25**
Registration timing: **prospective**

Last update: **2024-09-15, 1403/06/25**
Update count: **0**

Registration date

2024-09-15, 1403/06/25

Registrant information

Name

Amir Rezazadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 729 8761

Email address

rezazadeh.am@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-22, 1403/08/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the therapeutic effects of bromelain-based supplement (Anaheal 1200 GDU enteric coated) on ecchymosis, swelling and pain after blepharoplasty in patients over 18 years old versus placebo

Public title
Evaluation of the therapeutic effects of bromelain-based supplement (Anaheal 1200 GDU enteric coated) after blepharoplasty

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Post blepharoplasty surgery patients Age above 18 years Ability to fill out an informed consent form Ability to follow the approved protocol to participate in the study

Exclusion criteria:
Allergy to pineapple, celery, carrot and fennel Pregnant and breastfeeding women Severe kidney failure (GFR<30) Severe liver failure (Child pugh B, C) Haemophilia Use of anticoagulant, antiplatelet and thrombolytic drugs Patients with irregular heartbeat and tachycardia Asthma patients

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, volunteers were individually assigned into two Groups (drug and placebo) using block randomization. It should be noted that 4 sized blocks are used in this method. Block randomization was done using the "https://www.sealedenvelope.com/simple-randomiser/v1/lists" website and the obtained specialized codes (including two English letters and one number) were assigned to each candidate in the order of entry.

Blinding (investigator's opinion)
Double blinded

Blinding description
Block randomization is performed by an independent individual who labels the drugs and placebos based on the generated codes. The physician and the study executor administer the drug/placebo to patients using the corresponding code, without knowing the type of treatment. Similarly, patients receive treatment based on the specified code and are unaware of their treatment type. It is worth mentioning that the statistician is aware of the group allocations and uses the information provided by the independent individual to categorize patients into two groups and perform the statistical tests.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Research Ethics Committees of Pharmacy and Pharmaceutical Sciences - Islamic Azad University

Street address
No. 99, yasaman St., Yakhchal St, Shariati Ave.

City
Tehran

Province
Tehran

Postal code
1941933111

Approval date
2024-06-18, 1403/03/29

Ethics committee reference number
IR.IAU.PS.REC.1403.133

Health conditions studied

1

Description of health condition studied
Ptosis of eyelid

ICD-10 code
H02.40

ICD-10 code description
Unspecified ptosis of eyelid

Primary outcomes

1

Description
The amount of ecchymosis after blepharoplasty

Timepoint
At 1, 3, 7 and 14 days after surgery

Method of measurement
Based on the questionnaire, the evaluation of the amount of periorbital ecchymosis and the scoring is based on the extent and severity of ecchymosis from 0 to 5.

2

Description
The amount of swelling after blepharoplasty

Timepoint

At 1, 3, 7 and 14 days after surgery

Method of measurement

Based on the questionnaire, the evaluation of the amount of periorbital swelling and The scoring is based on the severity of swelling from 0 to 4.

Secondary outcomes

1

Description

Side effects of Anaheal 1200 GDU

Timepoint

At 1 and 14 days after surgery

Method of measurement

Ask the patient

2

Description

The amount of pain after blepharoplasty

Timepoint

At 1, 3, 7 and 14 days after surgery

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group: includes 25 patients over 18 years old after blepharoplasty. After checking the inclusion and exclusion criteria of the study and obtaining informed consent, patients will receive one Anaheal 1200 GDU enteric coated capsule (manufactured by Salamat Parmoon Amin Company) per day in addition to the standard treatment including painkillers, anti-inflammatories and antibiotics. Patients are examined on days 1, 3, 7 and 14 to evaluate changes in ecchymosis, swelling and pain.

Category

Treatment - Drugs

2

Description

Control group: includes 25 patients over 18 years old after blepharoplasty. After checking the inclusion and exclusion criteria of the study and obtaining informed consent, patients will receive a placebo containing Avicel and having the same appearance as the original medication in addition to the standard treatment including painkillers, anti-inflammatories and antibiotics. Patients are examined on days 1, 3, 7 and 14 to evaluate changes in bruising, swelling and pain.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Saadatabad Surgery Center

Full name of responsible person

Dorsasadat Miri

Street address

Unit 7, Floor 4, No 128, Ketab Sq, West Sarv Ave

City

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1998999999

Phone

+98 912 724 3262

Email

dorsamiri792000@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Amir Rezazadeh

Street address

No. 99, Yakhchal Street, Shariati Avenue.

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Grant name

Grant code / Reference number

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

No

Title of funding source

Salamat Parmoon Amin Pharmaceutical company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dorsa sadat Miri

Position
Pharmacy student

Latest degree
A Level or less

Other areas of specialty/work
Medical Pharmacy

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No. 99, yasaman St., Yakhchal St, Shariati Ave.

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Amir Rezazadeh

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Email
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Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Kamyab Andarzbakhsh

Position
Clinical cooperator of the study

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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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
The final results of scoring the condition of the ecchymosis, swelling, pain and related parameters

When the data will become available and for how long
After publishing the related article in international journals

To whom data/document is available
Researchers in the field of medicine and pharmacy

Under which criteria data/document could be used
Development of science and expand evidence related to treatment in further research

From where data/document is obtainable
Islamic Azad University, Tehran Medical Sciences Branch: Respected applicants can use the following method to receive their desired documents or data from Islamic Azad University, Tehran Medical Sciences Branch: Communication with the Research and Technology Unit: To receive information and documents related to research and clinical trials, applicants can refer to the Research and Technology Unit of the university. Postal Address: Administrative Building Address: Administrative Building of Tehran Islamic Azad University of Medical Sciences, Gol Yakh Street, Ayeneh Boulevard, Amir Pabarja Street, Qolhak , Dr. Shariati Street, Tehran, Iran. Contact Number: 26602642-3 Email: rezazadeh.am@iums.ac.ir Website: www.tms.iau.ir

What processes are involved for a request to access

data/document

Request Submission and Documentation/Data Retrieval Process from the Research and Technology Department: Request Submission: Applicants must submit their request in writing, including full details (type of documents or data, purpose of request, and related supplementary information) to the university's Research and Technology Department. Method of Submission: Requests can be delivered in person to the Research and Technology Department. Postal Address: Administrative Building Address: Administrative Building of Tehran Islamic Azad University of Medical Sciences, Gol Yakh Street, Ayeneh Boulevard, Amir Pabarja Street, Qolhak , Dr. Shariati Street, Tehran, Iran. Phone Number: 26602642-3.Request Review: After receiving the request, the Research and Technology Department staff will review it. This review includes assessing the content of the request and determining if additional information is needed. If further clarification or adjustments are required, the applicant will be contacted via email or phone. Document/Data Delivery: Once prepared, the requested documents or data will be delivered to the applicant either in person or electronically. Delivery Methods: Electronic: Sent via email. Final Delivery Timeframe: 1 to 2 business days after preparation.Follow-up and Communication: Applicants can contact the Research and Technology Department at any stage of the process to follow up on the status of their request. Phone Number: 26602642-3.stimated Overall Timeframe for Receiving Documents/Data: From the time the request is submitted until the final receipt of documents or data, the process typically takes between 15 and 20 business days."

Comments