Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical evaluation of the efficacy of purified bioactive peptides from Spirulina Platensis algae on the healing of wounds after periodontal flap surgery (double-blinded randomized clinical trial)

Protocol summary

Study aim

Clinical evaluation of the effectiveness of purified bioactive peptides from Spirulina platensis algae in healing process of wounds caused by periodontal flap surgery with a double-blind randomized clinical trial:

Design

Target group: patients referred to the periodontics department of Tabriz university of medical Sciences, faculty of dentistry Sample size: 30 patients diagnosed with periodontitis and indicated for periodontal flap surgery in at least 2 separate areas.

Settings and conduct

After purification of spirulina protein and enzymatic hydrolysis with free enzymes and the production of gel containing spirulina bioactive compounds, the effects of spirulina bioactive compounds will be checked on patients who are candidates for periodontal flap surgery by comparing the variables in the two areas of the gel used with the control area.

Participants/Inclusion and exclusion criteria

Having a favorable general health condition Being available during the 12 weeks of study Non- smoker patients Diagnosis of periodontitis and indication of periodontal flap surgery Pregnant women People who had used antibiotics and anti-inflammatory drugs within a month before surgery Patients who use orthodontic appliances Patients using the removable prosthesis Patients with intraoral pathological conditions Patients with a history of allergic reaction to health care products

Intervention groups

One of the surgical sites will be randomly selected as the intervention group and the tested substance will be used in this area. The other surgical site will be randomly selected as the intervention group and no substance will be used in this area.

Main outcome variables

swelling, gum color, pocket probe depth, clinical attachment loss, bleeding index, plaque index, amount of pain experienced, type of pain, number of painkillers used, bleeding gums

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221021056257N1**
Registration date: **2022-11-09, 1401/08/18**
Registration timing: **prospective**

Last update: **2022-11-09, 1401/08/18**
Update count: **0**

Registration date

2022-11-09, 1401/08/18

Registrant information

Name

Pouya Almassi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-12, 1401/08/21

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical evaluation of the efficacy of purified bioactive peptides from Spirulina Platensis algae on the healing of wounds after periodontal flap surgery (double-blinded randomized clinical trial)

Public title
Clinical evaluation of the efficacy of purified bioactive peptides from Spirulina Platensis algae on the healing of wounds after periodontal flap surgery (double-blinded randomized clinical trial)
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having a favorable general health condition Being available during the 12 weeks of study Non- smoker patients Diagnosis of periodontitis, as defined by at least three non-contiguous interproximal pockets with pocket depth (PPDs) greater than 4mm or other radiographic evidence such as alveolar bone loss Patients who show PPD ≥ 6mm after non-surgical treatment and periodontal surgery is indicated.
Exclusion criteria:
Pregnant women People who had used antibiotics and anti-inflammatory drugs within a month before surgery Patients who use orthodontic appliances Patients using the removable prosthesis Patients with intraoral pathological conditions Patients with 5 or more decayed teeth Patients who had participated in another study during the last 1 month Patients with a history of allergic reaction to health care products Patients who are forbidden to eat or drink liquids for 4 hours due to medical conditions
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
1
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
Presence of at least 2 separate sites with the indication of periodontal flap surgery in the mouth
Randomization (investigator's opinion)
Randomized
Randomization description
The sample selection method in the stage of allocating the type of treatment is randomized controlled sampling. In this method, the list of qualified people will be entered into Excel software and people will be randomly selected from the statistical population.
Blinding (investigator's opinion)
Double blinded
Blinding description
For blinding, Sealed envelope will be used and it will be given to the doctor by the patient. In other words, in this study, the surgical site is selected randomly and after opening the envelope, the doctor is going to use a gel containing spirulina bioactive compounds for the wound on one side, and the wound on the other side is considered as a control, and no special substance will be used. Also, the study is double-blind, and the evaluating student and the patient will not know about the case and the control.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Tabriz University of Medical Sciences
Street address
Research development and coordination center (RDCC), faculty of medicine, Tabriz university of medical sciences, Attar Neyshaburi St., Golgasht, St. Azadi St.
City
Tabriz
Province
East Azarbaijan
Postal code
5166/15731
Approval date
2022-10-10, 1401/07/18
Ethics committee reference number
IR.TBZMED.REC.1401.654

Health conditions studied

1

Description of health condition studied
Wounded tissue caused by periodontal flap surgery
ICD-10 code
T81.3
ICD-10 code description
Disruption of wound, not elsewhere classified

Primary outcomes

1

Description
Clinical variables evaluated after surgery include soft tissue swelling, gum color, pocket probe depth, clinical attachment loss, bleeding index, plaque index. Also, during the first 7 days after surgery, patients will complete a questionnaire to evaluate post-surgery complaints, which includes the amount of pain experienced, the type of pain, the number of painkillers taken, swelling of the mucous membrane and swelling of the face, and swelling and bleeding of the gum.

Timepoint
Examining the results of wound healing 1, 4 and 8 weeks following the surgery

Method of measurement
In order to check the amount of Swelling, the number 0 will be used for the absence of Swelling, the number 1 for moderate Swellingand 2 for significant Swelling. In order to evaluate the color of the gums, while comparing with the opposite side, the numbers 0 will be used for no redness, 1 for moderate redness and 2 for significant redness. To measure the depth of the probe pocket and CAL, the reference of these measurements will be from the Cementoenamel Junction. Bleeding index and Plaque index will be measured on 6 surfaces of the involved teeth and finally the measurements will be presented as an average. The presence or absence of bleeding during the probe will be recorded with two scales: 0 for no bleeding and 1 for bleeding. The presence or absence of plaque will also be measured with the same scale along the gingival margin. Also, to measure the variables of the questionnaire, in order to check the level of pain, the Visual Analogue Scale, which is a visual analog index with a degree of pain from 0 to 10, will be used. The amount of swelling of the mucous membrane and face will be asked with two options: no swelling and high swelling, and the presence or absence of bleeding in the area after surgery will be asked. The patient is requested not to refer to the information of the previous days when completing the questionnaire daily.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One of the surgical sites will be randomly selected as the intervention group and the tested substance will be used in this area.

Category
Treatment - Drugs

2

Description
Control group: the other surgical site will be randomly selected as the intervention group and no substance will be used in this area.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dentistry faculty of Tabriz university of medical sciences, department of periodontics

Full name of responsible person
Dr. Masoumeh Faramarzi

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Dentistry Faculty of Tabriz university of medical sciences, Golgasht St., Azadi Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
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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
Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Maryam Kouhsoltani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

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