

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Evaluation of probiotic supplementation effect on anxiety, inflammatory factors and oxidative stress biomarkers in patients undergoing third molar surgery

Protocol summary

Study aim

improvement the quality of treatment reduce the cost of treatment

Design

The clinical trial has a control group, with factorial groups, three blind strains and patients are randomly selected so that the clinical caregiver gives half of the samples as a placebo and half as a probiotic supplement. Phase 3 is on 50 patients.

Settings and conduct

This project is done in Kashan Dental School. blood sampling is performed first to measure the level of inflammatory and anxiety factors before the intervention. Then, for one month, one group receives a bioflora probiotic supplement and the other group receives a placebo. After one month, surgery is performed. And factor levels are re-measured to compare whether we have a greater reduction in inflammatory and anxiety factor levels with probiotic supplements. In this study, neither the patients, nor the person performing the surgery, nor the person analyzing the results knew the type of medication received.

Participants/Inclusion and exclusion criteria

Entry conditions: patients having more than 18 years_ patients having impacted third molar exit conditions: having inflammation or mental disorders- Taking probiotics during the last three months

Intervention groups

There are two groups. In both groups, blood sampling is performed first to measure the level of inflammatory and anxiety factors before the intervention. Then, for one month, one group receives a bioflora probiotic supplement and the other group receives a placebo. After one month, surgery is performed. And factor levels are re-measured to compare whether we have a greater reduction in inflammatory and anxiety factor levels with probiotic supplements.

Main outcome variables

NO Malondialdehyde Total antioxidant capacity Total Glutathione high-sensitivity C-reactive protein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210811052144N1**

Registration date: **2022-01-24, 1400/11/04**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-24, 1400/11/04**

Update count: **0**

Registration date

2022-01-24, 1400/11/04

Registrant information

Name

Vahid Kiani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5360 2257

Email address

vahidkiyani448@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-10, 1400/10/20

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of probiotic supplementation effect on anxiety, inflammatory factors and oxidative stress biomarkers in patients undergoing third molar surgery

Public title

Evaluation of probiotic supplementation effect on anxiety, inflammatory factors and oxidative stress biomarkers in patients undergoing third molar surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

patients having impacted third molar

Exclusion criteria:**Age**

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Patients and all people involved in writing and implementing the plan are kept blind. Just clinical caregiver are aware about the kind of drug.

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Ethics committee of Kashan University of Medical Sciences

Street address

Kashan, Qutb Ravandi Blvd, Beheshti Hospital

City

Kashan

Province

Isfahan

Postal code

8715985191

Approval date

2018-09-23, 1397/07/01

Ethics committee reference number

IR.KAUMS.REC.1397.067

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

Anxiety caused by wisdom tooth surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

NO

Timepoint

Beginning and end of the intervention

Method of measurement

Spectrophotometry

2**Description**

Malondialdehyde

Timepoint

Beginning and end of the intervention

Method of measurement

Spectrophotometry

3**Description**

Total antioxidant capacity

Timepoint

Beginning and end of the intervention

Method of measurement

Spectrophotometry

4**Description**

Total Glutathione

Timepoint

Beginning and end of the intervention

Method of measurement

Spectrophotometry

5

Description

high-sensitivity C-reactive protein

Timepoint

Beginning and end of the intervention

Method of measurement

ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Recipient of bioflora probiotic - product of takgene company - contains Lactobacillus acidophilus, Bifidobacterium Bifidum, Bifidobacterium Lactis and Bifidobacterium Langum - Dose: 1/8 × 10⁹ CFU / Capsule - How to use: once a day for one month

Category

Treatment - Drugs

2

Description

Control group: recipient of Placebo - one a day for a month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry Kashan Faculty of Dentistry of Kashan University of Medical Sciences

Full name of responsible person

Doctor Amirsalar Sayedyahosseini

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Qotb Ravandi Blvd., Kashan Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

امير سالار سيد ياحسين

Street address

Qotb Ravandi Blvd., Kashan Town

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Province

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Email

amirsalar.sayedyahosseini@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Vahid Kiani

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Doctor Amirsalar Sayedyahosseini

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Latest degree

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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

Undecided - It is not yet known if there will be 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