Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effects of zinc gluconate supplementation on several genes expression, the serum level of inflammatory factors, quality of life, and disease activity in patients with Behcet syndrome: double-blind randomized controlled clinical trial

Protocol summary

Study aim
To determine the effects of zinc gluconate supplementation on several genes expression, serum level of inflammatory factors, quality of life, and disease activity in patients with Behcet syndrome

Design
Double-blind randomized controlled clinical trial (RCT) with parallel design in phase 2-3 on 52 patients with Behcet's syndrome. The STATA software will be used for randomization using ralloc command

Settings and conduct
A double-blind (participants and researchers) RCT will be performed on 52 Behcet's syndrome patients referred to the Rheumatology Clinic of Tabriz University of Medical Sciences. After random allocation, the intervention group will receive 1 tablet of zinc gluconate (30 mg of elemental zinc) daily and the control group will receive similar placebo for 12 weeks. For blinding, coding of containers is performed by a third person. At the beginning and end of the intervention, 5 cc of fasting blood samples will be collected and international questionnaire of physical activity, quality of life, disease activity and 3-day food record will be completed

Participants/Inclusion and exclusion criteria
Participants: 52 people with Behcet's syndrome of both genders. Inclusion criteria: Aged 18 to 50 years, ability to give informed consent Exclusion criteria: Intake of supplements less than 70%, change in the dosage and type of medication received during the study, pregnancy, lactation, history of chronic diseases and consumption of nutritional supplements during one month prior to the study

Intervention groups
The intervention group will receive 1 daily tablet of 30 mg elemental zinc (231 mg zinc gluconate tablet) and the control group will receive similar placebo (cornstarch, and microcrystalline cellulose) for 12 weeks

Main outcome variables
Inflammatory and antioxidant parameters, quality of life and disease activity

General information

Reason for update
To revise the respondent person

Acronym

IRCT registration information
IRCT registration number: **IRCT20100606004105N30**
Registration date: **2020-08-02, 1399/05/12**
Registration timing: **prospective**

Last update: **2022-07-29, 1401/05/07**
Update count: **2**

Registration date
2020-08-02, 1399/05/12

Registrant information

Name
Beit Allah Alipour

Name of organization / entity
Health & Nutrition Faculty

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

2020-09-01, 1399/06/11

Actual recruitment end date

2020-11-18, 1399/08/28

Trial completion date

2021-02-16, 1399/11/28

Scientific title

The effects of zinc gluconate supplementation on several genes expression, the serum level of inflammatory factors, quality of life, and disease activity in patients with Behcet syndrome: double-blind randomized controlled clinical trial

Public title

Effect of zinc in treatment of Behcet syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 18 to 50 years (premenopausal woman) Diagnosis of Behcet's disease by a rheumatologist according to IBCD (The International Criteria for Behcet’s Disease) which vascular, eyes, and joints complications indicate the severity of the disease Patients who want to participate in the study

Exclusion criteria:

Pregnancy and lactation History of diabetes and other chronic diseases History of other autoimmune diseases Taking nutritional supplements and antioxidants and alpha lipoic acid during the month before the study

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **52**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

After reaching the inclusion criteria, individuals will be randomly divided into two groups of intervention and placebo by blocking method. Blocking will be performed based on gender and age and whereby the two groups will be matched in terms of age and gender. The four blocks will be created by STATA statistical software using ralloc command, which will be identified by the letters A, B, C, D. The assigned group is not known before the individual assignment.

Blinding (investigator's opinion)

Double blinded

Blinding description

All tablets (zinc and placebo) in the same shape and color are placed and labeled in the containers by a third person, and two codes are given to individuals, and the codes will be unknown to the researcher until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5165687386

Approval date

2020-06-29, 1399/04/09

Ethics committee reference number

IR.TBZMED.REC.1399.356

2

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

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East Azarbaijan

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Approval date

2021-04-12, 1400/01/23

Ethics committee reference number

IR.TBZMED.REC.1400.070

Health conditions studied

1

Description of health condition studied

Behcet Syndrome

ICD-10 code

M35.2

ICD-10 code description

Behcet's disease

Primary outcomes

1

Description

Toll-like Receptor-2 gene expression

Timepoint

Before and the end of the intervention (twelfth week)

Method of measurement

Real time PCR

2

Description

Toll-like Receptor-4 gene expression

Timepoint

Before and the end of the intervention (twelfth week)

Method of measurement

Real time PCR

3

Description

Toll-like Receptor-2 protein expression

Timepoint

Before and the end of the intervention (twelfth week)

Method of measurement

Flow cytometry

4

Description

Toll-like Receptor-4 protein expression

Timepoint

Before and the end of the intervention (twelfth week)

Method of measurement

Flow cytometry

5

Description

Serum level of tumor necrosis factor-alpha

Timepoint

Before and the end of the intervention (twelfth week)

Method of measurement

ELISA

6

Description

Serum level of zinc

Timepoint

Before and the end of the intervention (twelfth week)

Method of measurement

Atomic absorption spectroscopy

7

Description

NLRP3 gene expression

Timepoint

Before and the end of the intervention (twelfth week)

Method of measurement

Real time PCR

8

Description

Caspase-1 gene expression

Timepoint

Before and the end of the intervention (twelfth week)

Method of measurement

Real time PCR

9

Description

Serum level of interleukin-1 beta

Timepoint

Before and the end of the intervention (twelfth week)

Method of measurement

ELISA

10

Description

Serum level of malondialdehyde

Timepoint

Before and the end of the intervention (twelfth week)

Method of measurement

ELISA

11

Description

Serum level of C-reactive protein

Timepoint

Before and the end of the intervention (twelfth week)

Method of measurement

ELISA

Secondary outcomes

1

Description

Quality of life

Timepoint

Before, middle (sixth week) and end of intervention (twelfth week)

Method of measurement

Behçet’s disease quality-of-life (BD-QoL) questionnaire

2

Description

Disease activity

Timepoint

Before, middle (sixth week) and end of intervention

(twelfth week)

Method of measurement

Behcets Disease Activity Form

Intervention groups

1

Description

Intervention group: one zinc gluconate tablet daily (120 mg each tablet containing 30 mg elemental zinc) with a meal for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo (microcrystalline cellulose): 1 tablet (120 mg each) with a meal for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology Clinic of Imam Reza Hospital

Full name of responsible person

Amir Hossein Faghfouri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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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

Beitullah Alipour

Position

Professor of nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Position
Professor of Nutrition, in Faculty of Nutrition and Food Sciences

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Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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Professor of nutrition

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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
Not applicable

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