Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of curcumin supplementation on nutritional status, glucose and lipid pattern, blood pressure, inflammatory status, oxidative stress, infection, and early graft function in patients after kidney transplantation

Protocol summary

Study aim

Determining the effects of curcumin supplementation on nutritional status, glucose and lipid pattern, blood pressure, inflammatory status, oxidative stress, hematological parameters, infection, and initial renal function in patients after kidney transplantation

Design

Double-blind RCT with parallel design in phase 2-3 on 40 kidney transplant recipients. The STATA software will be used for randomization using ralloc command

Settings and conduct

This study will be performed in Montaserieh Hospital of Mashhad. In this study, researchers, clinical caregivers, and participants are kept blind.

Participants/Inclusion and exclusion criteria

The age range of 18-60 years People receiving kidneys from a deceased donor Complete and informed consent to participate in the research project People who do not have other diseases that increase oxidative stress, such as IBD, liver cirrhosis, tumors, cancer People who only had a kidney transplant. Do not take curcumin, turmeric, omega-3 supplements, vitamin E, and C supplements within one month before the start of the study. Do not take antiepileptic drugs within a month before the start of the study; People with cognitive disorders such as Alzheimer's

Intervention groups

Patients in the intervention group will be given a can of curcumin capsules sufficient for 6-week. Patients received one capsule containing 500 mg of curcumin (C3 Complex, Sami Labs Ltd., Indi) and 5 mg of piperine (95% piperine, Sami Labs Ltd., Indi). Patients in the placebo group are also given a can of placebo capsules that are similar in shape and size to curcumin capsules and contain 505 mg of maltodextrin (C3 Complex, Sami Labs Ltd., Indi) for 12 weeks.

Main outcome variables

Nutritional status; Sugar and lipid pattern; blood pressure; Inflammatory condition; Oxidative stress; Hematological characteristics; Infection and primary kidney function

General information

Reason for update

Modifying the expected start and end date of illness

Acronym

IRCT registration information

IRCT registration number: **IRCT20110123005670N29**
Registration date: **2022-06-22, 1401/04/01**
Registration timing: **prospective**

Last update: **2023-05-23, 1402/03/02**
Update count: **1**

Registration date

2022-06-22, 1401/04/01

Registrant information

Name

Ali Tarighat-Esfanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 914 300 5895

Email address

tarighata@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-22, 1401/07/30

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of curcumin supplementation on nutritional status, glucose and lipid pattern, blood pressure, inflammatory status, oxidative stress, infection, and early graft function in patients after kidney transplantation

Public title
Evaluation of the effect of curcumin in patients after kidney transplantation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range 18-60 years People receiving kidneys from a deceased donor Complete and informed consent to participate in the research project People who do not have other diseases that increase oxidative stress, such as inflammatory bowel disease, liver cirrhosis, tumors and cancer People who only had a kidney transplant Do not take curcumin, turmeric and omega-3 supplements, vitamin E and C supplements within one month before the start of the study Do not take antiepileptic drugs within a month before the start of the study
Exclusion criteria:
People with cognitive disorders such as Alzheimer's
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
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 age (18-48, 60-48) and sex (male and female) 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 capsules (curcumin 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
golgasht Ave., Tabriz university of medical sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5155668474
Approval date
2022-06-01, 1401/03/11
Ethics committee reference number
IR.TBZMED.REC.1401.238

Health conditions studied

1

Description of health condition studied
patients after kidney transplantation
ICD-10 code
Z94.0
ICD-10 code description
Kidney transplant status

Primary outcomes

1

Description
Blood sugar
Timepoint
At the beginning of the study and at the end of the study
Method of measurement
Biochemical testing

2

Description

lipid profile

Timepoint

At the beginning of the study and at the end of the study

Method of measurement

Biochemical testing

3

Description

blood pressure

Timepoint

At the beginning of the study and at the end of the study

Method of measurement

Biochemical testing

4

Description

Glomerular filtration rate

Timepoint

At the beginning of the study and at the end of the study

Method of measurement

Biochemical testing

5

Description

delay graft function

Timepoint

From the beginning of the study to the end of the first week

Method of measurement

Need dialysis during the first week after transplantation

6

Description

slow graft function

Timepoint

From the beginning of the study to the end of the tenth day

Method of measurement

Serum creatinine greater than 2.5 mg/dL on day 10 after transplantation

7

Description

Occurrence of acute graft rejection

Timepoint

From the beginning of the study to the end of the study

Method of measurement

Permanent return to dialysis, re-transplantation or death with an active transplant

8

Description

Incidence of viral infections

Timepoint

During the study

Method of measurement

Diagnosis by the treating physician

Secondary outcomes

1

Description

weight

Timepoint

Beginning and end of the study

Method of measurement

With minimal clothing and without shoes and using Seca scales with an accuracy of 0.1 kg

2

Description

height

Timepoint

Beginning and end of the study

Method of measurement

Shoeless by the meter mounted to the wall with an accuracy of 0.1 cm

3

Description

waist circumference

Timepoint

Beginning and end of the study

Method of measurement

In the middle of the area between the lowest rib and the highest part of the pelvis at the end of natural exhalation using an inelastic tape measure without pressure on the body surface

4

Description

Length of hospital stay

Timepoint

during study

Method of measurement

Number of hospitalization days

5

Description

Leukopenia

Timepoint

Beginning and end of the study

Method of measurement

By counting the WBC

6

Description

Thrombocytopenia

Timepoint

Beginning and end of the study

Method of measurement

With platelet count less than 150,000 per microliter

7

Description
Neutropenia
Timepoint
Beginning and end of the study
Method of measurement
With a neutrophil count of less than 1500 per microliter

Intervention groups

1

Description
Intervention group: Intervention group: Curcumin capsules, one capsule containing 500 mg of curcumin (C3 complex, Sami Labs Ltd., Indi) daily with 5 mg of piperine (black pepper extract containing 95% piperine, Sami Labs Ltd., Indi) during this study. It lasts 12 weeks
Category
Treatment - Other

2

Description
Control group: Placebo capsules, which are similar in shape and size to curcumin capsules and contain 505 mg of maltodextrin (C3 complex, Sami Labs Ltd., Indi), are given daily for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Montaserie organ transplantation hospital
Full name of responsible person
Mohammad Nosrati
Street address
In front of the Radio and Television Conference Hall, Imam Khomeini Ave., Golestan Blvd., Mashhad., Khorasan Razavi
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nosratim@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Parviz Shahabi
Street address
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz
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nosratim@tbzmed.ac.ir
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. Ali Tarighat Esfanjani
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Mohammad Nosrati-Oskouie

Position
Ph.D candidate

Latest degree
Master

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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