Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluating the Effectiveness of Nanocurcumin Capsules on Mucositis in Patients Undergoing Hematopoietic Stem Cell Transplantation: A Randomized Triple-blind Placebo controlled Clinical trial

Protocol summary

Study aim

Determining the effect of nanocurcumin capsules on mucositis in patients undergoing autologous and allogeneic transplantation

Design

A placebo-controlled, triple-blind, randomized, phase 3 clinical trial on 110 patients. A block random number table is used for randomization.

Settings and conduct

Location: The Bone Marrow Transplantation Department of Taleghani Hospital, Tehran. The intervention group will receive 120 mg of nanocurcumin daily and the control group will receive placebo. Patients, outcome assessor and data analyser will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion: Age 18 to 70 years. Adequate performance status, i.e. Eastern Cooperative Oncology Group (ECOG) score from 0 to 2. Ability to swallow and take capsules orally at the time of intervention and the possibility of taking them for at least one week after conditioning. Patients' agreement to standard mucositis prevention care according to the center's protocol Written informed consent. Exclusion: Known hypersensitivity to Curcumin, Turmeric, or components of the nanomicelle product. Chronic systemic corticosteroid use at a dose equivalent to >10 mg prednisone daily for 14 days prior to conditioning. Regular use of supplements or herbs with anti-inflammatory-antioxidant effects for 7 days prior to conditioning. Stable oral anticoagulant therapy or dual antiplatelet therapy that cannot be adjusted. AST or ALT > 3 times the ULN, or total bilirubin > 2 times the ULN, or eGFR < 30 mL/min/1.73 m^2. Concurrent participation in another interventional trial that directly affects mucositis, sleep, appetite, or supportive care.

Intervention groups

Intervention group receive 3 capsules daily of nanocurcumin and Control group receive 3 capsules daily of placebo from two days before the start of chemotherapy until the engraftment and resolution of mucositis.

Main outcome variables

Who mucositis grading scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100127003210N33**
Registration date: **2026-04-29, 1405/02/09**
Registration timing: **prospective**

Last update: **2026-04-29, 1405/02/09**
Update count: **0**

Registration date

2026-04-29, 1405/02/09

Registrant information

Name

Maria Tavakoli Ardakani

Name of organization / entity

Faculty of pharmacy, Shaid Beheshti University of Medical Sciences

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date
2028-05-21, 1407/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the Effectiveness of Nanocurcumin Capsules on Mucositis in Patients Undergoing Hematopoietic Stem Cell Transplantation: A Randomized Triple-blind Placebo controlled Clinical trial

Public title
Evaluating the Effectiveness of Nanocurcumin Capsules on oral ulcer in Patients Undergoing Hematopoietic Stem Cell Transplantation: A Randomized Triple-blind Placebo controlled Clinical trial
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 70 years. Confirmation of HSCT candidacy by the transplant team. Adequate performance status, i.e. Eastern Cooperative Oncology Group (ECOG) score from 0 to 2. Ability to swallow and take capsules orally at the time of intervention and the possibility of taking them for at least one week after conditioning. Patients' agreement to standard mucositis prevention care according to the center's protocol (prevention: chlorhexidine and normal saline mouthwash, treatment: diphenhydramine + AlMg + nystatin + lidocaine cocktail and, if needed and available, gelclair mouthwash and mucosamine spray). Written informed consent.
Exclusion criteria:
Known hypersensitivity to Curcumin, Turmeric, or components of the nanomicelle product. Chronic systemic corticosteroid use at a dose equivalent to >10 mg prednisone daily for 14 days prior to conditioning. Regular use of supplements or herbs with anti-inflammatory-antioxidant effects or containing Piperine for 7 days prior to conditioning, including high doses of vitamins A-C-E, selenium, non-study turmeric products, ginger, chamomile. Stable oral anticoagulant therapy or dual antiplatelet therapy that cannot be adjusted. Single low-dose aspirin use is acceptable and will be recorded. AST or ALT > 3 times the upper limit of normal, or total bilirubin > 2 times the upper limit of normal, or eGFR < 30 mL/min/1.73 m². Concurrent participation in another interventional trial that directly affects mucositis, sleep, appetite, or supportive care. Pregnancy or lactation.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
After obtaining informed consent, eligible patients are divided into two separate strata based on the type of transplant: autologous and allogeneic. In each stratum, randomization is performed with four-way random blocks and a 1:1 allocation ratio to the two arms of nanocurcumin (Group A) and placebo (Group B). The randomization sequence in each stratum is generated by computer and provided to the independent pharmacist in the form of coded block lists.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study is triple-blinded; patients, outcome assessor and data analyzer are unaware of the type of intervention (nanocurcumin or placebo) and only the pharmacist responsible for randomization has access to the code list. Randomization codes are kept in sealed, tamper-evident envelopes and remain confidential until data collection is complete and the database is locked, and will only be broken if necessary for safety or after completion of the primary analysis. Nanocurcumin and placebo capsules are identical in shape, size, color, and odor, and are distinguished only by unique alphanumeric codes on the packaging so that the allocation is not recognizable to the clinical team and patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Faculty of Pharmacy - Shahid Beheshti University of Medical Sciences
Street address
Faculty of Pharmacy, Shahid Beheshti University of Medical Science, Valiasr St., Hashemi Rafsanjani Highway intersection., Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1996835113
Approval date
2026-04-18, 1405/01/29

Ethics committee reference number
IR.SBMU.PHARMACY.REC.1405.015

Health conditions studied

1

Description of health condition studied
Patients with various Blood Malignancies who are candidates for Hematopoietic Stem Cell Transplantation.
ICD-10 code
T86.0
ICD-10 code description
Complications of bone marrow transplant

Primary outcomes

1

Description
Determining the effect of nanocurcumin capsules on mucositis in patients undergoing autologous and allogeneic transplantation
Timepoint
From the onset of mucositis to the resolution of mucositis
Method of measurement
WHO mucositis grading scale

Secondary outcomes

1

Description
Determining the effect of nanocurcumin on the incidence and severity of oral mucositis in patients undergoing autologous and allogeneic transplantation.
Timepoint
From the onset to the resolution of mucositis.
Method of measurement
WHO mucositis grading scale

2

Description
Determining the effect of nanocurcumin on the onset and termination time of oral mucositis in patients undergoing autologous and allogeneic transplantation.
Timepoint
From the onset to the resolution of mucositis.
Method of measurement
WHO mucositis grading scale

3

Description
Determining the effect of nanocurcumin on the host incidence and severity of gastrointestinal mucositis in patients undergoing autologous and allogeneic transplantation.
Timepoint
From the onset to the resolution of mucositis.
Method of measurement
based on CTCAE v 5.0 criteria

4

Description
Determining the effect of nanocurcumin on the appetite of patients undergoing autologous and allogeneic transplantation.
Timepoint
Before intervention initiation, during chemotherapy or neutropenic period, after engraftment
Method of measurement
The Council on Nutrition Appetite Questionnaire (CNAQ)

5

Description
Determining the effect of nanocurcumin on sleep of patients undergoing autologous and allogeneic transplantation.
Timepoint
Before intervention initiation, during chemotherapy or neutropenic period, after engraftment
Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

6

Description
Determining the effect of nanocurcumin on the need for narcotic analgesics in patients undergoing autologous and allogeneic transplantation.
Timepoint
From the beginning of intervention until resolution of mucositis and engraftment of patients.
Method of measurement
Total morphine equivalent dose of prescribed opioids

7

Description
Determining the effect of nanocurcumin on the need for total parenteral nutrition in patients undergoing autologous and allogeneic transplantation.
Timepoint
From the beginning of intervention until resolution of mucositis and engraftment of patients.
Method of measurement
Duration of need for total parenteral nutrition in patients

8

Description
Determining the safety and side effects of nanocurcumin in patients undergoing autologous and allogeneic transplantation
Timepoint
Weekly from the onset of intervention until resolution of mucositis and engraftment of patients
Method of measurement
Questionnaire based on common adverse effect of nanocurcumin based on studies

9

Description
Determining the effect of nanocurcumin on days of neutropenic fever in patients undergoing autologous and allogeneic transplantation

Timepoint
From the onset of intervention until resolution of mucositis and engraftment of patients.

Method of measurement
Measurement of body temperature of patients during neutropenic period

Intervention groups

1

Description
Intervention group: Receive 3 capsules daily (one after each meal) of nanocurcumin containing 40 mg of curcuminoids in a highly bioavailable nanomicelle medium from Exir Nano Sina company, from two days before the start of chemotherapy until the engraftment and resolution of mucositis.

Category
Treatment - Drugs

2

Description
Control group: Receive 3 capsules daily (one after each meal) of placebo, from two days before the start of chemotherapy until the engraftment and resolution of mucositis.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani General Hospital

Full name of responsible person
Dr. Maria Tavakoli Ardakani

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Taleghani General Hospital, Next to Shahid Beheshti University of Medical Sciences, Shahid Arabi St, Yemen St, Shahid Chamran highway, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Maria Tavakoli Ardakani

Position
Professor

Latest degree
Specialist

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
No - There is not a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Laboratory findings of patients along with statistical analysis can be shared without providing patients' names.
When the data will become available and for how long
6 month after publishing the results, primary outcome data will be released.
To whom data/document is available
Doctors and other researchers
Under which criteria data/document could be used
People such as hospital staff or other medical staff such as nurses and clinical pharmacists can use this information.
From where data/document is obtainable
Researchers can contact the following email to receive information: mariatavakoli@yahoo.com
What processes are involved for a request to access data/document
People who intend to use the information must be affiliated with reliable organizations and their requests should be submitted through these organizations. In this context, there is a need for an introduction letter from the desired center.
Comments