

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Nano-curcumin supplementation on clinical symptoms and signs, length of hospital stays and inflammation level in moderate acute pancreatitis.

Protocol summary

Study aim

To determine the effect of Nano-curcumin supplementation on clinical symptoms and signs, length of hospital stays and inflammation level in moderate acute pancreatitis

Design

A randomized, double-blinded, controlled clinical trial with a parallel group design of 42 patients. Random number table will be used for randomization.

Settings and conduct

42 eligible patients with moderate acute pancreatitis will randomly assign to consume two soft gels daily each containing 40 mg of Nano-curcumin or placebo for two weeks. Both groups will also receive the standard medical treatment in hospital. Patients' blood samples will be taken before and after the intervention to determine CBC, kidney and liver function, blood sugar, electrolytes and CRP. Clinical signs during the hospitalization period will be recorded and the two groups will also be compared in terms of local complications and length of hospital stay. In this study participants and investigators will be blinded and concealment will be done by a third person.

Participants/Inclusion and exclusion criteria

People with a clinical diagnosis of moderate acute pancreatitis presenting within 72 hours of onset of pain and in the age range of 18-75 who are able to intake soft gels orally and desire to participate in the study will be included in the study. While people having pregnancy or breastfeeding, any history of allergy to Curcumin, acute exacerbation of chronic pancreatitis, prior antioxidant therapy, severe co-morbid illness, active gastrointestinal ulcers or those who take anticoagulants will be excluded from the study.

Intervention groups

1- Nano-curcumin group: receiving 80mg of Nano-curcumin daily in the form of 40mg soft gels for 14 days

2-Placebo group: placebo soft gels containing MCT oil for 14 days

Main outcome variables

Length of hospital stay, Serum CRP level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100524004010N33**

Registration date: **2021-11-25, 1400/09/04**

Registration timing: **prospective**

Last update: **2021-11-25, 1400/09/04**

Update count: **0**

Registration date

2021-11-25, 1400/09/04

Registrant information

Name

Azita Hekmatdoost

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
National Institute of Nutrition Research

Country

Iran (Islamic Republic of)

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+98 21 2293 0824

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-31, 1400/10/10

Expected recruitment end date

2022-05-10, 1401/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Nano-curcumin supplementation on clinical symptoms and signs, length of hospital stays and inflammation level in moderate acute pancreatitis.

Public title
The effect of Nano-curcumin supplementation on clinical symptoms and signs, length of hospital stays and inflammation level in moderate acute pancreatitis.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Having desire to participate in the study Age range of 18-75 Patients with a clinical diagnosis of moderate acute pancreatitis (specifically, a history of acute abdominal pain associated with a greater than threefold elevation of the serum amylase and/or computed tomographic evidence of acute pancreatitis) presenting within 72 hours of onset of pain. Having the ability to intake soft gels orally
Exclusion criteria:
Pregnancy or breastfeeding History of allergy to Curcumin Acute exacerbation of chronic pancreatitis Taking antioxidant supplements such as vitamin C, vitamin E or omega 3 Severe co-morbid illness (liver disease including Cirrhosis and Hepatitis, renal failure (Cl Cr <30)) Active gastrointestinal ulcers Taking anticoagulants such as Heparin, Clopidogrel, Dipyridamole, Warfarin and Ticlopidine

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomized into Nano-curcumin group or placebo according to the table of random numbers at the beginning of the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients won't know if they are receiving the Nano-curcumin or a placebo soft gel and for double-blinding

the study, the bottles containing the relevant soft gels will be concealed as A and B by a third person at the beginning of the study, and none of the research team members will know the type of soft gels received by each group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the National Institute of Nutritional Research and Food Industry

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2021-10-20, 1400/07/28

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1400.057

Health conditions studied

1

Description of health condition studied

Moderate Acute Pancreatitis

ICD-10 code

K85

ICD-10 code description

Acute pancreatitis

Primary outcomes

1

Description

Length of hospital stay

Timepoint

Through study completion, an average of two weeks

Method of measurement

Counting the number of admission days in hospital based on medical records

2

Description

Serum C-reactive protein level

Timepoint

At the first and the end of the 2nd week of the study

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

Secondary outcomes

1

Description

Abdominal pain severity

Timepoint

At the beginning and the end of the study (14th day)

Method of measurement

Visual analog scale (VAS)

2

Description

Serum ALT concentration

Timepoint

At the beginning and the end of the study (14th day)

Method of measurement

Enzymatic method

3

Description

Serum ALT concentration

Timepoint

At the beginning and the end of the study (14th day)

Method of measurement

Enzymatic method

4

Description

Serum ALK-P concentration

Timepoint

At the beginning and the end of the study (14th day)

Method of measurement

Enzymatic method

5

Description

Serum Creatinine concentration

Timepoint

At the beginning and the end of the study (14th day)

Method of measurement

Enzymatic method

6

Description

Blood Urea Nitrogen (BUN) concentration

Timepoint

At the beginning and the end of the study (14th day)

Method of measurement

Enzymatic method

7

Description

Serum Amylase level

Timepoint

At the beginning and the end of the study (14th day)

Method of measurement

Enzymatic method

8

Description

Serum Lipase level

Timepoint

At the beginning and the end of the study (14th day)

Method of measurement

Enzymatic method

Intervention groups

1

Description

Intervention group: Will take 80 mg of Nano-curcumin daily in the form of two soft gels each contains 40 mg of Nano-curcumin (Product of Exir Nano Sina Company) orally for two weeks.

Category

Other

2

Description

Control group: Will take two placebo capsules daily, which are similar in shape and taste to Nanocurcumin soft gel, orally for two weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani General Hospital

Full name of responsible person

Amir Sadeghi

Street address

Ayatollah Taleghani Educational Hospital, Araabi St., Yaman Ave, Chamran High Way, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

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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
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Position
Professor
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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

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