Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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-Plasebo 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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Azita Hekmatdoost
Position
Professor
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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