Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effects of nano curcumin in eradicating and improving the symptoms of patients with Helicobacter pylori infection

Protocol summary

Study aim
Determining the effects of nano curcumin in eradicating and improving the symptoms of patients with Helicobacter pylori infection

Design
Clinical trial with control group, with parallel groups, three blind, randomized

Settings and conduct
patients with H. pylori infection who referred to the gastroenterology clinic of birjand Vali-e-Asr Hospital during 1401-1402.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Having informed consent to enter the study 2- People aged 18 to 70 with digestive symptoms such as dyspepsia, nausea, vomiting and epigastric burning suspected of Helicobacter pylori, who will refer to the specialized gastroenterology clinic of Vali-e-Asr Hospital in Birjand. 3-Any person who does not meet any of the exclusion criteria will be included in the study if they are satisfied Exclusion criteria: 1- History of anti-H.pylori treatment 2- Antibiotic use 3- Acute gastrointestinal bleeding 4- Proton pump inhibitor use in the last month 5- Pregnancy or breastfeeding 6- Allergy to turmeric and ginger family 7- Known cancers including stomach 8- People with HIV 9- Recent surgeries 10- Alcohol consumption and the presence of systemic diseases such as cardiovascular diseases and diabetes

Intervention groups
the nano curcumin capsule is given to the intervention group every eight hours for 14 days in addition to the Helicobacter pylori treatment, and the Plasio capsule is given to the control group every eight hours along with the Helicobacter pylori treatment.

Main outcome variables
Hong Kong dyspepsia index; Helicobacter pylori eradication rate

General information

Reason for update
-

Acronym

IRCT registration information
IRCT registration number: **IRCT20230131057297N1**
Registration date: **2023-05-09, 1402/02/19**
Registration timing: **prospective**

Last update: **2025-04-23, 1404/02/03**
Update count: **1**

Registration date
2023-05-09, 1402/02/19

Registrant information
Name
Mohammad Ali Mahdiabadi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 915 561 5743
Email address
mahdiabadi_ma@bums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-01, 1402/03/11

Expected recruitment end date
2024-03-15, 1402/12/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effects of nano curcumin in eradicating and improving the symptoms of patients with Helicobacter pylori infection

Public title
Effects of nanocurcumin in treatment of patients with Helicobacter pylori

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having informed consent to enter the study People aged 18 to 70 years with digestive symptoms such as dyspepsia, nausea, vomiting and epigastric burning Any person who does not have any of the exclusion criteria

Exclusion criteria:
History of anti-Helicobacter pylori treatment Taking antibiotics Acute gastrointestinal bleeding Proton pump inhibitor use in the last month Pregnancy or breastfeeding Allergy to turmeric and ginger family Known cancers including stomach People with HIV Recent surgeries Alcohol consumption and the presence of systemic diseases such as cardiovascular diseases and diabetes

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In the current study, sampling will be available from among the eligible and with informed consent. The eligible people will be randomly assigned to one of the two intervention and control groups. First, the intervention group was coded with the letter A and the control group with the letter B, and then using the website www. sealedenvelope.com/simple-randomiser/v1/lists randomization list was prepared by selecting a sample size of 80 (two groups of 40) and permuted block randomization method (block size=4) (20 blocks of 4). Then, through the obtained randomization list, the subjects included in the study will be assigned to one of the two groups, A or B. For example, suppose that in the first four blocks, the permutation method is ABBA, so the first and fourth samples will be assigned to group A and the second and third samples to group B, and the same will continue until the last sample (80nd person).

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients will not know the type of prescribed medicine, as one group will receive medicine and the other group will receive a placebo. The shape and appearance of the drug and placebo are completely similar to each other. Each patient will receive a code at the beginning of entering the plan, which will indicate the drug that he will receive, and until the end of the study, none of the researchers will know about the drug prescribed for each patient. Also, the person performing the statistical analysis will analyze the patients' information in two groups labeled A and B.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Birjand University of Medical Sciences

Street address
Ghaffari St

City
Birjand

Province
South Khorasan

Postal code
9717853577

Approval date
2022-09-26, 1401/07/04

Ethics committee reference number
IR.BUMS.REC.1401.238

Health conditions studied

1

Description of health condition studied
Helicobacter pylori infection

ICD-10 code
B98.0

ICD-10 code description
Helicobacter pylori [H.pylori] as the cause of diseases classified to other chapters

Primary outcomes

1

Description
Hong Kong dyspepsia index

Timepoint
before the intervention, immediately after the

intervention and one month after the end of the intervention

Method of measurement

Hong Kong dyspepsia index

2

Description

Helicobacter pylori eradication rate

Timepoint

One month after treatment

Method of measurement

Stool antigen test

Secondary outcomes

1

Description

Frequency of clinical symptoms (dyspepsia, nausea, vomiting and epigastric burning) in the intervention and placebo groups

Timepoint

The beginning and end of the study

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Nanocurcumin capsule 40 mg every 8 hours (Exir Nano Sina Company) + Levofloxacin 500 mg daily + Omeprazole 20 mg every 12 hours + Amoxicillin 1 gr every 12 hours for 14 days

Category

Treatment - Drugs

2

Description

Control group: Nanocurcumin capsule (placebo) every 8 hours (Exir Nano Sina Company) + levofloxacin 500 mg daily + omeprazole 20 mg every 12 hours + amoxicillin 1 gram every 12 hours for 14 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Raziyeh Sadat Abolhasani

Street address

Ghaffari St

City

Birjand

Province

South Khorasan

Postal code

9717964151

Phone

+98 56 3162 2035

Email

Abolhasani73@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mohammad Reza Miri

Street address

Ghaffari St

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3238 1200

Email

research@bums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Mohammadali mahdiabadi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gastroenterology and Hepatology of adults

Street address
Ghaffari St
City
Birjand
Province
South Khorasan
Postal code
9717964151
Phone
+98 56 3162 2035
Email
mahdiabadi_ma@bums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Mohammadali mahdiabadi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gastroenterology and Hepatology of adults
Street address
Ghaffari St
City
Birjand
Province
South Khorasan
Postal code
9717964151
Phone
+98 56 3162 2035
Email
mahdiabadi_ma@bums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Mohammadali mahdiabadi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gastroenterology and Hepatology of adults
Street address
Ghaffari St
City
Birjand
Province
South Khorasan
Postal code
9717964151
Phone
+98 56 3162 2035
Email
mahdiabadi_ma@bums.ac.ir

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