

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of alphapinen addition to quadruple therapy for the eradication of *Helicobacter pylori* gastrointestinal infectious

#### Protocol summary

##### Study aim

To determine whether adding alphapinen capsule as adjuvant to quadruple regimen in patients with *Helicobacter pylori* infection will increase the eradication rate.

##### Design

Design of the study is a double-blind, placebo-controlled, randomized control single center clinical trial. Patients with age more than 18 years old infected with *Helicobacter pylori* will be enrolled the study. Patients whom are not desired to enroll the study will be excluded. In this research, 78 patients were randomly divided into two control and intervention groups by Microsoft Excel software and a code was allocated to each one of them.

##### Settings and conduct

This study is conducted as placebo controlled double blinded randomized clinical trial in taleqani hospital participants and researcher all has been blinded. All patients will receive quadruple therapy for eradication of *Helicobacter pylori*. In addition patients will receive either alphapinen 10 mg/d capsule or placebo randomly. After 4 weeks rate of *Helicobacter pylori* eradication will be determined in each groups and compared.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Infected patients with *Helicobacter pylori* with obtaining written consent form  
Exclusion criteria: pregnancy or breastfeeding

##### Intervention groups

Intervention group (alphapinen): *Helicobacter pylori* infected patients compatible with inclusion/exclusion criteria administrated with 10 mg alphapinen daily for 4 weeks. Control group (Alphapinen placebo): *Helicobacter pylori* infected patients compatible with inclusion/exclusion criteria administrated with 1 tablet of placebo daily for 4 weeks.

##### Main outcome variables

Eradication of *Helicobacter pylori* rate (in percent)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20121021011192N15**

Registration date: **2023-06-21, 1402/03/31**

Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**

Update count: **0**

##### Registration date

2023-06-21, 1402/03/31

##### Registrant information

##### Name

Mohammad Abbasinazari

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8887 3704

##### Email address

m\_abbasi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-23, 1402/05/01

##### Expected recruitment end date

2023-10-23, 1402/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effect of alphapinen addition to quadruple therapy for the eradication of Helicobacter pylori gastrointestinal infectious

## Public title

Effect of alphapinen addition to quadruple therapy for the eradication of Helicobacter pylori gastrointestinal infectious

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients who infected with Helicobacter pylori on the basis of doing urease breath test Obtaining written informed consent

### Exclusion criteria:

Patients with previous history of allergy to alphapinen

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor

## Sample size

Target sample size: **76**

## Randomization (investigator's opinion)

Randomized

## Randomization description

1:1 randomization, centralized web-based randomization and according to the entry and exit criteria, through random allocation by balanced block method, individuals are divided into two groups of control and experimental. Using Random Sequence Generator, groups are created and people are placed in one of these two groups based on the reference sequence.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participants, principle investigator, healthcare providers (Physicians, nurses) who care for participants during the trial, data collectors and outcome assessors all are blinded by providing placebo capsules in same size, shape color, odor and package with capsules of alphapinen which organized just by one responsible co-researcher has no involvement in running study.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of pharmacy, nursing and midwifery of Shahid Beheshti university of medical science

##### Street address

School of Pharmacy, Nyayesh junction, Valiasr street

##### City

Tehran

##### Province

Tehran

##### Postal code

1996835113

#### Approval date

2023-05-28, 1402/03/07

#### Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.020

## Health conditions studied

### 1

#### Description of health condition studied

Infectious with Helicobacter pylori

#### ICD-10 code

B96.81

#### ICD-10 code description

Helicobacter pylori [H. pylori] as the cause of diseases classified elsewhere

## Primary outcomes

### 1

#### Description

Eradication of Helicobacter pylori

#### Timepoint

1month after finishing drugs

#### Method of measurement

Assesing the urease breath test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Addition of alphapinen orally 10 mg/d to eradication regimen of Helicobacter pylori for 2 weeks

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Addition of alphapinen placebo 1 capsule

per day orally to eradication regimen of Helicobacter pylori for 2 weeks

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Talighani hospital

**Full name of responsible person**

Mohammad Abbasinazari

**Street address**

School of Pharmacy, Nyayesh junction, Valiasr street

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**Email**

m\_abbasi@sbmu.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Hassan Yazdanpanah

**Street address**

School of Pharmacy, Nyayesh junction, Valiasr street

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yazdanpanah@sbmu.ac.ir

**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**

Mohammad Abbasinazari

**Position**

full professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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**Person responsible for updating data**

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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**

Yes - There is a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

All data can be shared after deidentified

**When the data will become available and for how long**

starting in July 2024

**To whom data/document is available**

only available for people working in academic institutions

**Under which criteria data/document could be used**

with written consent

**From where data/document is obtainable**

Sending email to: m\_abbasi@sbmu.ac.ir

**What processes are involved for a request to access data/document**

Sending email to: m\_abbasi@sbmu.ac.ir

**Comments**