

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Assessment of the safety and efficacy of Cornelian cherry in the treatment of gastric intestinal metaplasia a pilot study

#### Protocol summary

##### Study aim

To assess the safety and efficacy of Cornelian cherry in the treatment of intestinal metaplasia

##### Design

non-randomized, pilot study on 30 patients; no control group will be assessed since gastric intestinal metaplasia has no pre-approved treatment.

##### Settings and conduct

the study is neither blinded nor randomized. the study will be conducted in gastroenterology clinics of shiraz university of medical sciences.

##### Participants/Inclusion and exclusion criteria

Adult patients older than 20 years old with intestinal metaplasia who are referred to gastroenterology clinics of Shiraz University of Medical Sciences will be included in our study. The exclusion criteria will be: patients younger than 20 years old, pregnancy, lactation, the existence of gastric cancer, calcium oxalate nephrolithiasis, and the history of any surgical interventions performed on the stomach such as Billroth I and II

##### Intervention groups

after treatment of H.pylori infection, the patients with GIM will be asked to consume 50 Cornelian cherries (one cup) each day for two months. the patients will undergo upper endoscopy before and after the treatment

##### Main outcome variables

the existence of gastric intestinal metaplasia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230811059114N1**

Registration date: **2023-08-23, 1402/06/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-08-23, 1402/06/01**

Update count: **0**

##### Registration date

2023-08-23, 1402/06/01

##### Registrant information

###### Name

Seyyed Mohammad Kazem Hosseiniasl

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 917 793 3211

###### Email address

kazemhosseiniasl@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-08-23, 1402/06/01

##### Expected recruitment end date

2024-03-19, 1402/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment of the safety and efficacy of Cornelian cherry in the treatment of gastric intestinal metaplasia a pilot study

##### Public title

Cornelian Cherry in Gastric Intestinal Metaplasia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Adult patients older than 20 years old with intestinal metaplasia who are referred to gastroenterology clinics of Shiraz University of Medical Sciences

**Exclusion criteria:**

patients younger than 20 years old pregnancy lactation existence of gastric cancer calcium oxalate nephrolithiasis history of any surgical interventions performed on the stomach such as Billroth I and II

**Age**

From **20 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **25**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

**Street address**

9th floor, building No.2, School of Medicine, Zand St., Shiraz, Iran

**City**

shiraz

**Province**

Fars

**Postal code**

7134845794

**Approval date**

2023-02-21, 1401/12/02

**Ethics committee reference number**

IR.SUMS.MED.REC.1401.569

**Health conditions studied**

1

**Description of health condition studied**

gastric intestinal metaplasia

**ICD-10 code**

K31.9

**ICD-10 code description**

Disease of stomach and duodenum, unspecified

**Primary outcomes**

1

**Description**

the existence of gastric intestinal metaplasia in histopathologic samples

**Timepoint**

before intervention and two months and one year after intervention

**Method of measurement**

histopathologic samples of biopsies taken through endoscopy

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: receiving 50 (one cup) cornelian cherry each day for two months, half of which with lunch and the other half with dinner

**Category**

Treatment - Other

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Gastroenterology Clinics of Shiraz University of Medical Sciences

**Full name of responsible person**

Seyed Mohammad Kazem Hosseini-Asl

**Street address**

Department of Internal Medicine, Namazi Hospital, Namazi sq., Shiraz, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

7193613311

**Phone**

+98 71 3647 4332

**Fax**

**Email**

kazemhosseiniasl@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mohammad Hashem Hashempur

**Street address**

Deputy of Research and Technology, seventh floor,  
central building of Shiraz University of Medical  
Sciences, Zand st., Shiraz, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

7134814336

**Phone**

+98 71 3212 2430

**Email**

hashempurm@sums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz University of Medical Sciences

**Proportion provided by this source**

1

**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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Seyed Mohammad Kazem Hosseini-Asl

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Department of Internal Medicine, Namazi hospital,  
Namazi sq., Shiraz, Iran

**City**

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## Person responsible for scientific inquiries

### Contact

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Shiraz University of Medical Sciences

**Full name of responsible person**

Seyed Mohammad Kazem Hosseini-Asl

**Position**

Associate Professor

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Shiraz University of Medical Sciences

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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**

Not applicable

### **Data Dictionary**

Not applicable

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

the patients' information will be reported after the study

as cumulative data and after they will have been made anonymous

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

after the study which will take about one and a half year

### **To whom data/document is available**

all of the researchers

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

upon reasonable request, the researchers can ask for the data after they will have been made anonymous

### **From where data/document is obtainable**

the article will be published and the data can be accessed through email of the corresponding author

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

after indicating the reason why they want the data and their identity the data will be available to them which will take less than a week

### **Comments**