

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

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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

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7134814336

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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

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Person responsible for scientific inquiries

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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

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