

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Clinical evaluation of an Iranian traditional product (derived from plantago ovata) in the treatment of radiotherapy induced diarrhea Grade 1 to Grade 3

Protocol summary

Summary

Purpose ;Diarrhea is The most common manifestation of acute damage caused by radiation therapy that effective treatment remains unclear. In this study, we compare product derived from plantago ovata with standard drug loperamide in the treatment of diarrhea caused by radiotherapy. Design of study and performance: This study is open randomized clinical trial with control group (standard drug) in one center (Motahari Clinic) that perform On patients with histologically confirmed cancer and age> 18 years that experienced diarrhea with grade 1(Increase of <4 stools per day over baseline),grade 2(Increase of 4 - 6 stools per day over baseline) to grade3(increase of >=7-10 stools per day over baseline or stool incontinence), as described in Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0, after at least a fraction of radiotherapy. The main exclusion criteria are diarrhea or stool incontinence before the beginning of irradiation, grade 4 diarrhea, past history of gastrointestinal disorder known to cause diarrhea. 62 Samples select from target population that assign at least 31patients to each of two treatment arms. Patients randomly assign to receive either loperamide in a standard dosage or traditional drug ,paste product, two times daily for one week. All patients give a diary and instruct to record the daily medication taken, the number of loose bowel movements, occurrence of blood or mucus in stool, Duration of diarrhea therapy starting from the first day of administration of the study drug until complete disappearance of loose bowel movements and side effects of drugs on each treatment day. Follow up of every patient perform on a daily basis during the course of treatment by a therapist on the phone. The primary outcome assess as follows : complete response _complete resolution of diarrhea, partial response _ one to two diarrheas daily, no response _ three or more diarrheas daily.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015083123823N1**
Registration date: **2015-10-25, 1394/08/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-25, 1394/08/03

Registrant information

Name

Ali Tavakoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3233 1028

Email address

tavakkolia@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Governmental source(Shiraz University Of Medical Sciences)

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-03-15, 1394/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of an Iranian traditional product (derived from plantago ovata) in the treatment of radiotherapy induced diarrhea Grade 1 to Grade 3

Public title

Effect of an product derived from plantago ovata in the treatment of radiotherapy induced diarrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with Grade 1 to Grade 3diarrhea, as described in Common Terminology Criteria for Adverse Events (CTCAE) Version 4.0 and experienced during the 24-h period after a fraction of radiotherapy ;All patients had a histologically confirmed cancer ;age>18 years; absence of fever with white blood cell count of over 3,000/mm3. exclusion criteria: Patients with Grade 4 diarrhea; diarrhea or stool incontinence before the beginning of irradiation; renal failure; past history of gastrointestinal disorder known to cause diarrhea ;presence of an active intraluminal gastrointestinal tumor

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University Of Medical Sciences

Street address

Zand Strret

City

Shiraz

Postal code

Approval date

2015-05-17, 1394/02/27

Ethics committee reference number

IR.SUMS.REC.1394.36

Health conditions studied

1

Description of health condition studied

radiotherapy induced diarrhea

ICD-10 code

k52.0

ICD-10 code description

Gastroenteritis and colitis due to radiation

Primary outcomes

1

Description

number of loose bowel movement (stool)

Timepoint

daily

Method of measurement

visual by paitent

Secondary outcomes

1

Description

Duration of diarrhea therapy

Timepoint

daily

Method of measurement

Recorded by patients in a special card

2

Description

side effects

Timepoint

daily

Method of measurement

Recorded by patients in a special card

Intervention groups

1

Description

samples select from target population that assign at least 31patients to each of two treatment arms. Patients in interventional group receive traditional drug ,paste product,12.5 gr two times daily for one week

Category

Treatment - Drugs

2

Description

Patients in control group receive loperamide in a standard dosage(2 mg per every bowel habit with maximum daily dose12 mg) for one week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Clinic

Full name of responsible person

Tavakoli Ali

Street address

Namazi Square,Zand Street

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University Of Medical Sciences

Full name of responsible person

Hashemi Basir

Street address

Zand Street

City

Shiraz

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

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University Of Mdicl Sciences

Full name of responsible person

Tavakoli Ali

Position

MD/phd student of traditional medicin

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty