

# 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

#### Street address

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tavakkolia@sums.ac.ir

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University Of Mdicl Sciences

##### Full name of responsible person

Omidvari Shapour

##### Position

Department Of Radiotherapy Oncology /Associate Professor

##### Other areas of specialty/work

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## Person responsible for updating data

#### Contact

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Tavakoli Ali

##### Position

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##### Other areas of specialty/work

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##### Fax

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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*