

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical Trial of malva Sylvestris L. formulation on intestinal side effects of pelvic cancers radiation

Protocol summary

Summary

Objectives: The aim of this study is investigating the effect of product of Malva Sylvestris on intestinal side effects of radiotherapy (radiation proctitis) Setting and conduct: In clinical trials, patients received pelvic radiation in Shohadaye Tajrish and Imam Khomeini Hospital in the first session of radiotherapy asked about frequency and severity of gastrointestinal symptoms, (with Acute Radiation Morbidity Scoring Criteria and visual analog scale) and then patients in two groups (case and control) receive drug or placebo from first session of radiotherapy until end of that and symptoms are evaluated using same criteria In the third week of treatment, end of treatment and again at the second week after irradiation. Participants including major eligibility criteria: patient should receive pelvic radiation; Age between 18 to 80 years excluding criteria: other natural therapy during the study; thrombotic diseases; Cardiovascular disease; Diabetes; Hypertension; Severe cognitive impairment; Psychotic disorder intervention: patient received drug and placebo in shape of sachet (12 mg in three doses) Outcome: Then Using statistical tests, the effectiveness of the product, are analyzed including diarrhea, tenesmus, urgency, rectal pain, anal irritation, bleeding and incontinence

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101011064N1**
Registration date: **2014-04-19, 1393/01/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-04-19, 1393/01/30

Registrant information

Name

Reihaneh Moeini

Name of organization / entity

Traditional medicine of Tehran university

Country

Iran (Islamic Republic of)

Phone

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r-moeini@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for education, faculty of Traditional Medicine, Tehran university of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2014-07-01, 1393/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial of malva Sylvestris L. formulation on intestinal side effects of pelvic cancers radiation

Public title

Evaluation of Malva Sylvestris. formulation on Radiation proctitis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients who are planned pelvic radiotherapy with impression of cancer Age over 18 years; Non Inclusion criteria: Other natural therapy

during the study; Thrombotic diseases; Known gastrointestinal disease before radiotherapy; severe Cardiovascular disease; uncontrolled Diabetes; severe Hypertension; Severe cognitive impairment; Psychotic disorder

Age

From **18 years** old to **80 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

none

Secondary trial Id

none

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the School of Traditional Medicine, Tehran University of Medical Sciences

Street address

Research institu of Islamic & Traditional medicin

City

Tehran

Postal code

Approval date

2012-12-09, 1391/09/19

Ethics committee reference number

933 / ط / 26 پ

Health conditions studied

1

Description of health condition studied

Radiation proctitis

ICD-10 code

k62.7

ICD-10 code description

Radiation proctitis

Primary outcomes

1

Description

Anal Burning

Timepoint

Every 3 weeks

Method of measurement

visual analog scale 0-10

2

Description

Diarrhea

Timepoint

every 3 week

Method of measurement

visual analog scale 0-10

3

Description

Fecal incontinence

Timepoint

every 3 weeks

Method of measurement

visual analog scale

4

Description

Fecal urgency

Timepoint

every 3 weeks

Method of measurement

visual analog scale

5

Description

anal bleeding

Timepoint

every 3 weeks

Method of measurement

visual analog scale

6

Description

Excretion of mucous

Timepoint

every 3 weeks

Method of measurement

visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group patient should use sachet of Malva, 12 mg in 3 dosage that should brewed in boiled water, from first day of radiation until end of that.(each pocket is 4 g)

Category

Prevention

2

Description

All patients in control group take powder of placebo which is designed for this study in 4 mg packets in three dosages a day orally with a glass of hot water.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Cancer Center

Full name of responsible person

Reihaneh Moeini

Street address

Imam Khomeini Hospital,End of Keshavarz Blv.,
Tehran, Iran

City

Tehran

2

Recruitment center

Name of recruitment center

Radiation Center of Shohadae Tajrish Hospital

Full name of responsible person

Reihaneh Moeini

Street address

Ghods Sq., Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for education, faculty of ,Traditional
Medicine, Tehran university

Full name of responsible person

Mohammadreza Fartookzadeh

Street address

Office of Vice Chancellor for education, Third floor,
Faculty of Traditional Medicine, Behesht St., Vahdat
Eslami St. (South Hafiz), Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for education, faculty of ,Traditional
Medicine, Tehran university

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

Faculty of Traditional Medicine, Tehran university of
medical science

Full name of responsible person

Reihaneh Moeini

Position

PhD Assistant

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran university of medical science

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Farshid Farhan

Position

Professor of Radiotherapy- Oncology

Other areas of specialty/work

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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

Person responsible for updating data

Contact

Name of organization / entity

Faculty of traditional medicine, Tehran university of
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Full name of responsible person

Reihane Moeini

Position

PhD assistant

Other areas of specialty/work

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