

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of Plantago Major compared to placebo on prevention of radiation induced acute mucositis in head and neck cancer patients

Protocol summary

Study aim

Effect of Plantago syrup on the prevention of acute radiation-induced mucositis in patients with head and neck cancer

Design

Randomized, double blind clinical trials with control group and parallel group design. The sample size is 46.

Settings and conduct

This study is conducted in two centers (Isfahan hospitals and Kashan Yasrebi Hospital). The study was a randomized double-blind clinical trial. Patients are randomly (using the balance block method) divided into two groups: intervention and control. The patient and the examination physician are blinded. Drug and placebo are similar in shape, packaging, color, smell and taste.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with 17-65 years old in both sexes; candidate for radiotherapy for head & neck cancers; life expectancy over 1 year; Good performance status in ECOG questionnaire; at least 4 areas in radiation therapy (RT) fields. Non-inclusion criteria: Patients with organic & suppressive disorders; use of drugs effective on salivary glands, smoking or alcohol consuming; history of radiotherapy for mouth and oropharynx in the last 6 months.

Intervention groups

In intervention group: Plantago syrup; 7.5 cc after meal; three times per day for 7 weeks. In control group: placebo syrup; 7.5 cc after meal; three times per day for 7 weeks.

Main outcome variables

Mucositis; pain; quality of life; side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190312043027N1**

Registration date: **2019-08-14, 1398/05/23**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-14, 1398/05/23**

Update count: **0**

Registration date

2019-08-14, 1398/05/23

Registrant information

Name

Gholamreza Mohammadsoltani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3362 4281

Email address

rezamohammadsoltani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-22, 1397/07/30

Expected recruitment end date

2019-08-20, 1398/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Plantago Major compared to placebo on prevention of radiation induced acute mucositis in head and neck cancer patients

Public title

The effects of Plantago Major on prevention of radiation

induced acute mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for radiotherapy for head & neck cancer
Patients with 17-65 years old Life expectancy over 1 year
Good performance status in Eastern Cooperative
Oncology Group (ECOG) questionnaire At least 4 areas in
radiotherapy (RT) fields

Exclusion criteria:

Using alcohol Use of drugs affecting salivary gland
secretions, such as antidepressants, Opiates, anti-
hypertensives, anti-histamines. Use of mouthwash
solutions Smoking History of mouth and oropharynx
radiation therapy and chemotherapy in the last six
months. History of connective tissue diseases affecting
salivary glands such as Sjogren syndrome , Rheumatoid
arthritis and Lupus and immunodeficiency diseases
Grade 3-4 mucositis Candidiasis, oral herpes
Hospitalization or need to Total Parental Nutrition (TPN)
Dissatisfaction to continue participating in the study
Treatment failed Diabetes

Age

From **17 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomize individual blocks using random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

Drug and placebo in the form of syrup and without
mentioning the name of the drug in the pharmacy
company Sanabel , affiliated to the Center for Clinical
Trial Research of Traditional Medicine, Shahed
University, was provided by a third person who did not
participate in the rest of the study. The investigator and
team conducting research and evaluating outcomes, as
well as participants, did not know the type of contents of
syrup bottles.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical
Sciences

Street address

Basij Square., Arak., Markazi Province.

City

Arak

Province

Markazi

Postal code

8715973454

Approval date

2018-06-19, 1397/03/29

Ethics committee reference number

IR.ARAKMU.REC.1397.059

Health conditions studied

1

Description of health condition studied

Radiation-induced mucositis in head and neck cancer

ICD-10 code

K12.3

ICD-10 code description

Oral mucositis (ulcerative)

Primary outcomes

1

Description

mucositis

Timepoint

Baseline of radiation therapy; every week after initiation
of radiation therapy for 5 weeks and two weeks after
intervention terminated.

Method of measurement

Examination of oral cavity

2

Description

Pain

Timepoint

At the baseline and every week from first to seventh.

Method of measurement

Visual analogue scale of pain

3

Description

Quality of life

Timepoint

At the baseline and every week from first to seventh.

Method of measurement

EORTC questionnaire

Secondary outcomes**1****Description**

Side effects

Timepoint

Every week from first to seventh.

Method of measurement

Questionnaire

Intervention groups**1****Description**

Intervention group: Plantago syrup, three times per day, after each meal, each serving 7.5 cc, for 7 weeks.

Category

Treatment - Drugs

2**Description**

Control group: Placebo syrup, three times per day, after each meal, each serving 7.5 cc, for 7 weeks.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Isfahan Omid Hospital

Full name of responsible person

Simin Hemati

Street address

Omid Hospital, Motahari Ave., Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8414736631

Phone

+98 31 3235 0210

Email

Hematti@med.mui.ac.ir

2**Recruitment center****Name of recruitment center**

Yasrebi Hospital

Full name of responsible person

Mostafa Sarvizadeh

Street address

Ysrebi Hospital., Parastar Blvd., Ghotb ravandi Blvd.,
Kashan

City

Kashan

Province

Isfahan

Postal code

8715973454

Phone**Email**

info@yasrebihospital.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Basij Square., Arak., Markazi Province.

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3639

Fax

+98 86 3417 3645

Email

research@arakmu.ac.ir

Web page address

<https://arakmu.ac.ir/vcr/fa/page/3876>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

100

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**

Arak University of Medical Sciences

Full name of responsible person

Gholamreza Mohammadsoltani

Position

PhD Student of Iranian Traditional medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No.158, Mahvash Alley., Shariati St., Khomeini Shahr., Isfahan Province.

City

Khomeini Shahr

Province

Isfahan

Postal code

84147-36631

Phone

+98 31 3362 4574

Email

rezamohammadsoltani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Gholamreza Mohammadsoltani

Position

PhD Student of Traditional Iranian Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No.158 , Mahvash Alley.,Shariati St., Khomeini Shahr.,Isfahan Province

City

Khomeini Shahr

Province

Isfahan

Postal code

84147-36631

Phone

+98 31 3362 4574

Email

rezamohammadsoltani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Gholamreza Mohammadsoltani

Position

PhD Student of Traditional Iranian Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

No.158, Mahvash Alley.,Shariati St., Khomeini Shahr., Esfahan Province

City

Khomeini Shahr

Province

Isfahan

Postal code

84147-36631

Phone

+98 31 3362 4574

Email

rezamohammadsoltani@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

I Will be Decided For Information Publication

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available