Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 i conducted in two center (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

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Iran (Islamic Republic of)

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+98 31 3362 4281

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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 Sjugren 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.
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2

Recruitment center
Name of recruitment center
Yasrebi Hospital
Full name of responsible person
Mostafa Sarvizadeh
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Ysrebi Hospital., Parastar Blvd., Ghotb ravandi Blvd., Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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+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
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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