Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation and comparison of the effects of Aloe vera on prevention and treatment of radiotherapy induced mucositis- Isfahan 2021

Protocol summary

Study aim
Determining the effect of Aloe vera on the prevention and treatment of mucositis caused by head and neck radiotherapy

Design
Clinical trial with control group, with parallel groups, double-blind, random phase 2-3, 80 patients divided into 2 groups using randomized permutation block method and 40 people receive aloe vera and 40 people receive placebo

Settings and conduct
The study is performed in Isfahan and on those who refer to Seyed Al-Shohada Hospital. Blinding is done with the same drug and placebo packaging and coding.

Participants/Inclusion and exclusion criteria
Patients over 18 years of age newly diagnosed with head and neck cancers without previous history of radiotherapy and Karnovsky over 70

Intervention groups
The control group is given mouthwash containing Aloe vera and the control group is given a placebo with a similar appearance during the treatment period

Main outcome variables
The frequency distribution of mucosal symptoms varies from week to week in each patient receiving aloe vera and placebo.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201203049585N1**
Registration date: **2021-02-11, 1399/11/23**
Registration timing: **prospective**

Last update: **2021-02-11, 1399/11/23**
Update count: **0**

Registration date
2021-02-11, 1399/11/23

Registrant information
Name
Nadia Najafizade
Name of organization / entity
Country
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-23, 1399/12/05

Expected recruitment end date
2022-09-22, 1401/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation and comparison of the effects of Aloe vera on prevention and treatment of radiotherapy induced mucositis- Isfahan 2021

Public title
Effects of Aloe Vera on mucositis

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Indication of Head and Neck radiotherapy Lack of previous history of radiation Lack of any mucusitis due to

radiation or any other couses Lack of evidence of distant metastasis Karnofsky Performance Status at least 70 Not to use of NSAID or Steroids or other analgesics Absence of pregnancy At least 50 gray of radiation dose

Exclusion criteria:

Patient request to exit Patient die due to another reason Severe adverse effects

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the clinical caregiver who provides the medication and placebo and the researcher who enters the data into the checklist will be unaware of which group each patient is in. The drug and the placebo will be sidelined with the same appearance and packaging.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib St., Isfahan

City

Isfahan

Province

Isfehan

Postal code

8184917911

Approval date

2021-01-22, 1399/11/03

Ethics committee reference number

IR.MUI.MED.REC.139.973

Health conditions studied

1

Description of health condition studied

Head and Neck cancers

ICD-10 code

K12.33

ICD-10 code description

Oral mucositis (ulcerative) due to radiation

Primary outcomes

1

Description

RTOG grading of mucusitis

Timepoint

Record of RTOG grade before and every week of treatment and end of radiation

Method of measurement

RTOG grading questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: from the beginning of radiotherapy to the end of treatment, which lasts for an average of 6 weeks for each patient, patients are advised to gargle 5 cc of the received solution for 3 minutes 3 times a day. On the day of treatment, each patient is instructed on how to take the medicine and the empty medicine bottle is delivered and filled every two weeks according to the recommended dose. The aloe vera solution will contain pure aloe vera gel plus two-tenths of a percent methyl paraben and two-hundredths of a percent propyl paraben as a preservative.

Category

Treatment - Drugs

2

Description

Control group: they receive a placebo-containing bottle with the same appearance as the medicine in the same way.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Seyed al-shohada hospital

Full name of responsible person
Roya mobini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Roya Mobini

Position
Physician

Latest degree
Medical doctor

Other areas of specialty/work
Radiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after unidentified individuals
When the data will become available and for how long
6 month after publishing
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Use for meta analysis
From where data/document is obtainable
Seyed al-shohada hospital Roya mobini Roya.mobini@gmail.com 00989131819715
What processes are involved for a request to access data/document
Correspondence with Isfahan University of Medical Sciences and Department of Radiotherapy
Comments