

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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

Iran (Islamic Republic of)

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+98 31 3775 2366

Email address

nadianajafizade@med.mui.ac.ir

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 mucositis due to

radiation or any other causes 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

Isfahan

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 mucositis

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

Street address

Seyed al-shohada hospital, Motahari street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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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Person responsible for scientific inquiries

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Name of organization / entity

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Position

Physician

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Specialist

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Person responsible for updating data

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Other areas of specialty/work

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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