

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of curcumin on radiation induced mucositis

Protocol summary

Study aim

Effect of curcumin on radiation induced mucositis

Design

Patients in three groups receiving curcumin 0.1% mouthwash or curcumin capsule 40 mg or placebo mouthwash will be randomly divided into reciprocating blocks (each group of 20 people) and each patient will use mouthwashes belonging to their group 3 times a day or 40 mg capsule daily for 3 weeks. Patients will not use other therapies during this time. This is a prospective single blind randomized controlled clinical trial and will be performed on 30 patients who accidentally enter three groups of 20 people to control or interventions.

Settings and conduct

Patients admitted to the study will be selected from the patients of the Shahid Ramezanzadeh Radiation Therapy Center in Yazd will enter the study randomly.

Participants/Inclusion and exclusion criteria

Patients aged 18 to 65 years old with mucositis caused by receiving at least a dose of 50 gray of radiation during total radiotherapy and involvement of at least two parts of the mouth.

Intervention groups

Intervention group1: patients will be received 0.1% curcumin mouthwash 3 times a day for 3 weeks
Intervention group 2: patients will be received curcumin capsule 40 mg per day for 3
Control group: patients will be received placebo mouthwash 3 times a day for 3 weeks

Main outcome variables

Wounds - redness - pain and burning - severity and frequency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190810044500N17**

Registration date: **2021-08-13, 1400/05/22**

Registration timing: **prospective**

Last update: **2021-08-13, 1400/05/22**

Update count: **0**

Registration date

2021-08-13, 1400/05/22

Registrant information

Name

Fatemeh Saghafi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of curcumin on radiation induced mucositis

Public title

Effect of curcumin on radiation induced mucositis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with mucositis caused by radiotherapy and

chemotherapy Get at least a dose of 50 gray of radiation during the study At least two parts of the mouth are involved

Exclusion criteria:

Patients with certain diseases Unwillingness to continue participating in the study smoking Serious dental problems, bruising teeth and the presence of sharp fillings Presence of artificial teeth importing trauma Severe systemic disease such as uncontrolled diabetes With the start of radiation therapy, the patient should be treated by a physician other than for the usual treatment for mucositis. Simultaneous treatment with Target therapy drugs Infection

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to three groups of 20 curcumin mouthwash, curcumin tablets, and placebo by the permuted block method. Treatment assignments within blocks are determined so that they are random in order but that the desired allocation proportions are achieved exactly within each block. 12 blocks of 5 are considered. Generation of random codes using Permuted Block Randomization method will be done with the help of Random allocation software (version 1). The first person who is eligible to enter the study is given number one and likewise, the last eligible person is given number 60. By using the software-generated table, patients receive each intervention (A or B or C). In order to consider blinding in random allocation, the list is given to another person outside the study and using short message service (SMS) before assigning the type of treatment according to the number of eligible people is asked and thus people enter the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

The steps will be covered by the assessor. The first presenter identifies the sequence of assignments of patients according to the order of entry of the patients into the study and identifies them with A or B or C codes. The student then delivers the drugs to each individual patient

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional research Ethics Committee School of Medicine, Shahid Sadoughi University of Medical Sci

Street address

Shahid Sadoughi University of Medical Sciences, Shohaday Gomnam blvd.

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2020-09-13, 1399/06/23

Ethics committee reference number

IR.SSU.MEDICINE.REC.1399.112

Health conditions studied

1

Description of health condition studied

Mucositis

ICD-10 code

K12. 30

ICD-10 code description

Diseases of the digestive system

Primary outcomes

1

Description

Oral wound size

Timepoint

Before the intervention, after completion of the intervention

Method of measurement

Clinical examination

Secondary outcomes

1

Description

Pain or burning sensation in the mouth

Timepoint

Before intervention, after intervention

Method of measurement

Clinical examination and patient based on VAS criteria

2

Description

Redness

Timepoint

Before intervention, after intervention

Method of measurement

Clinical examination and patient based on VAS criteria

Intervention groups

1

Description

Intervention group1: patients will be received 0.1% curcumin mouthwash 3 times a day for 3 weeks

Category

Treatment - Drugs

2

Description

Intervention group 2: patients will be received curcumin capsule 40 mg per day for 3 weeks

Category

Treatment - Drugs

3

Description

Control group: patients will be received placebo mouthwash 3 times a day for 3 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ramazanzadeh Radiation Therapy Center in Yazd

Full name of responsible person

Shiva Ghadirian

Street address

Shahid Motahari Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

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Shahid Sadoughi University of Medical Sciences, Bahonar Ave.

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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

Yazd University of Medical Sciences

Proportion provided by this source

20

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

Yazd University of Medical Sciences

Full name of responsible person

shiva ghadirian abarghoyi

Position

University student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Full name of responsible person

Fateme Saghafi

Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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