

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of mouthwash of hydroalcoholic extract of 15% of Iranian oak jaft (*Quercus brantii*) on prevention, pain intensity and extent of oral mucosa in cancer patients undergoing chemotherapy and radiotherapy, a randomized trial study

Protocol summary

Study aim

Determining the effect of Iranian oak hydroalcoholic extract mouthwash on the prevention and management of oral mucositis in cancer patients undergoing chemotherapy and radiotherapy in Shahrekord Parsian Hospital and clinics.

Design

In the present study, a sampling method was used based on the census of all cancer patients referred, hospitalized or outpatients to the chemotherapy and radiotherapy departments of Shahrekord Parsian Hospital and clinics that met the conditions for inclusion in the study. Then by randomly allocating drug and placebo to all patients who meet the conditions for entering the study, the subjects were studied. The 15% hydroalcoholic extract of Iranian oak was prepared at the Medicinal Plant Research Center of Shahrekord University of Medical Sciences, and 40 135 cc glass containers containing medicine and 40 containers containing placebo were prepared and sealed according to British Pharmacopoeia (BP) instructions.

Settings and conduct

The method of coding was such that the researcher was blind to the contents and codes on the containers.

Participants/Inclusion and exclusion criteria

Entry criteria • Does not have any underlying immune system defects. • Be free of any mucositis during study entry. • Having informed and written consent from the patient or the patient's guardian to participate in the study • Age above 15 years • Definitive diagnosis of cancer by a specialist doctor • Undergoing chemotherapy or radiotherapy, but patients have not received radiotherapy or chemotherapy in the last three months

Intervention groups

All patients with inclusion criteria

Main outcome variables

Occurrence of pain, intensity of pain, intensity of mucositis

General information

Reason for update

Acronym

MDCHR

IRCT registration information

IRCT registration number: **IRCT20221028056322N1**

Registration date: **2022-11-28, 1401/09/07**

Registration timing: **retrospective**

Last update: **2022-11-28, 1401/09/07**

Update count: **0**

Registration date

2022-11-28, 1401/09/07

Registrant information

Name

Jafar Moghadassi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3333 5277

Email address

moghadas@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-21, 1400/03/31

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

2021-06-21, 1400/03/31

Actual recruitment end date

2022-01-20, 1400/10/30

Trial completion date

2022-02-03, 1400/11/14

Scientific title

The effect of mouthwash of hydroalcoholic extract of 15% of Iranian oak jaft (*Quercus brantii*) on prevention, pain intensity and extent of oral mucosa in cancer patients undergoing chemotherapy and radiotherapy, a randomized trial study

Public title

The effect of mouthwash of hydroalcoholic extract of Iranian oak jaft

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

does not have any underlying immune system defects. Be free of any mucositis at the time of entering the study. Having informed and written consent from the patient or the patient's guardian to participate in the study. Age above 15 years under chemotherapy or radiotherapy, but patients have not undergone radiotherapy or chemotherapy in the last three months.

Exclusion criteria:

Age below 15 years

Age

From 15 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 80

Actual sample size reached: 79

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, a sampling method was used based on the census of all cancer patients referred, hospitalized or outpatients to the chemotherapy and radiotherapy departments of Shahrekord Parsian Hospital and clinics that met the conditions for inclusion in the study. Then by randomly allocating drug and placebo to all patients who meet the conditions for entering the study, the subjects were studied.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The target population consisted of 80 people in the

present study, who were selected from among cancer patients referred, hospitalized or outpatients in the chemotherapy and radiotherapy departments of Parsian Shahrekord Hospital and clinics, using the census-based sampling method. Then, the patients were studied by simple random assignment of drug and placebo to all patients who meet the conditions for entering the study. Identical containers containing drug and placebo were coded by the Medicinal Plants Study Center of Shahrekord University of Medical Sciences under the supervision of respected professors of medicinal plants and kept in the refrigerator until delivery to the patients. The method of coding has been such that the researcher of the contents and the included codes

Placebo

Used

Assignment

Parallel

Other design features

In this study, random allocation of drugs was done. In parallel studies, random allocation of patients to two control and intervention groups was done.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of shahre kord university of Medical Sciences

Street address

Address: Shahrekord, Kashani Boulevard, University Headquarters, Building No. 2 Postal Code: 8815713471 Phone: 038-33342414 vcrt@skums.ac.ir

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Postal code

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Approval date

2021-05-06, 1400/02/16

Ethics committee reference number

IR.SKUMS.REC.1400.17

Health conditions studied**1****Description of health condition studied**

Oral mucositis caused by chemotherapy and radiotherapy

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Incidence rate, severity of pain and severity of oral mucositis

Timepoint

Before, one or two weeks after the intervention

Method of measurement

World Health Organization Mucositis Severity Measurement Tool and Pain Visual Analogue

Secondary outcomes

1

Description

Patient comfort level

Timepoint

Before, one or two weeks after the intervention

Method of measurement

Visual analogue of pain

Intervention groups

1

Description

Intervention group: In both intervention and control groups, drug or placebo was randomly assigned.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Radiotherapy department of Shahrekord Parsian Hospital and chemotherapy clinics of Dr. Amiri and Mas

Full name of responsible person

Dr. Jafar Moghdisi

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Shahrekord, Kashani Boulevard, University Headquarters, Building No. 2 Postal Code: 8815713471

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Elham Raisi

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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

Shahre-kord University of Medical Sciences

Proportion provided by this source

1

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

Shahre-kord University of Medical Sciences

Full name of responsible person

Mohammad Reza Kiani

Position

Master's student in internal surgery

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Other areas of specialty/work

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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

busy work

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available