Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Evaluating the effect of Achillea wilhelmsii oral rinse on chemoradiotherapy induced oral mucositis in head and neck cancer patients

Protocol summary

Study aim
Determining the effect of Achillea wilhelmsii oral rinse on chemoradiotherapy induced oral mucositis in head and neck cancer patients

Design
Randomized controlled clinical trial with parallel groups, double blinded, phase 3 study on 36 patients. Randomization by using random number table.

Settings and conduct
According to the inclusion and exclusion criteria, 36 patients referring to the radiotherapy ward of Mehraneh specialized clinic of Zanjan will be selected to participate in the study and will be divided into two groups of intervention and control randomly. From the first day of cancer treatment, the intervention group will use Achillea wilhelmsii mouthwash and the control group will use placebo. Patients in both groups should hold 15 ml of the prescribed mouthwash in their mouth for 3 minutes 4 times a day (after each meal and before bed) and then expel it. All the patients will undergo oral examination on days 0, 7, 14, 21, and 28 to evaluate the severity of the mucositis (according to World Health Organization scale). It should be noted that immediately after occurrence of grade 1 mucositis, in addition to using prescribed mouthwashes, patients in both groups will use Magic mouthwash, which is a common treatment for oral mucositis due to cancer treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1: Patients with head and neck malignancies Exclusion criteria: 1: Patients with oral mucositis 2: Patients with any systemic diseases other than head and neck malignancies 3: Patients with a history of allergy to Achillea wilhelmsii and medicinal plants 4: Patients with a history of chemotherapy or radiotherapy

Intervention groups
The intervention will be consisted of Achillea wilhelmsii mouthwash in the study group and placebo mouthwash in the control group.

Main outcome variables
Onset time of oral mucositis; severity of oral mucositis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180516039682N3**
Registration date: **2020-12-30, 1399/10/10**
Registration timing: **prospective**

Last update: **2020-12-30, 1399/10/10**
Update count: **0**

Registration date
2020-12-30, 1399/10/10

Registrant information

Name
Raheleh Akhavan rasoolzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 24 3314 8101

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-20, 1399/11/01

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

Evaluating the effect of Achillea wilhelmsii oral rinse on chemoradiotherapy induced oral mucositis in head and neck cancer patients

Public title

Effect of Achillea wilhelmsii oral rinse on chemoradiotherapy induced oral mucositis in head and neck cancers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with full consciousness Patients older than 18 years and younger than 60 years Patients with head and neck malignancies Patients undergoing chemotherapy and radiotherapy

Exclusion criteria:

Patients with oral mucositis Patients with any systemic diseases other than head and neck malignancies Patients with a history of allergy to Achillea wilhelmsii and medicinal plants Patients with a history of chemotherapy or radiotherapy Patients with xerostomia Use of drugs that reduce salivation Use of antibiotics, antifungals and systemic anti-inflammatory drugs Patients with malnutrition Smoking and alcohol consumption Use of dentures

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization: A person other than the investigator will blindly and randomly select a number from the random number table for each patient (by moving in all four directions up, down, left and right). If the selected number is even, the patient will assign to the control group and if the selected number is odd, the patient will assign to the intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, Achillea wilhelmsii mouthwash and normal saline mouthwash (placebo) will be available to patients in bottles of the same shape, size and dark color. Participants , outcome assessor and data analyzer will be blinded to the type of mouthwash and the patient's group. In this study, the pharmacist, as the person responsible for preparing mouthwash, will not be blinded to the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Central Station of Zanjan University of Medical Sciences, The Beginning of the Islamic Republic Boulevard, Azadi Square, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2020-09-01, 1399/06/11

Ethics committee reference number

IR.ZUMS.REC.1399.216

Health conditions studied

1

Description of health condition studied

Oral mucositis (Stomatitis)

ICD-10 code

K12

ICD-10 code description

Stomatitis and related lesions

Primary outcomes

1

Description

Onset time of oral mucositis

Timepoint

Days 0, 7, 14, 21 and 28 after starting cancer treatment

Method of measurement

Clinical examination by a dentist based on World Health Organization oral mucositis grading scale.

2

Description
Severity of oral mucositis
Timepoint
Days 0, 7, 14, 21 and 28 after starting cancer treatment
Method of measurement
Clinical examination by a dentist based on World Health Organization oral mucositis grading scale.

Secondary outcomes

1

Description
Patient's weight
Timepoint
Days 0, 7, 14, 21 and 28 after starting cancer treatment
Method of measurement
Using a digital scale

2

Description
Severity of oral pain
Timepoint
Days 0, 7, 14, 21 and 28 after starting cancer treatment
Method of measurement
Questionnaire

3

Description
Satisfaction with mouthwash
Timepoint
Days 0, 7, 14, 21 and 28 after starting cancer treatment
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: From the first day of cancer treatment, the intervention group will use Achillea wilhelmsii mouthwash. Achillea wilhelmsii mouthwash will be prepared in the pharmacognosy laboratory of the Faculty of Pharmacy of Zanjan University of Medical Sciences. Patients should hold 15 ml of the prescribed mouthwash in their mouth for 3 minutes 4 times a day (after each meal and before bed) and then expel it. Patients will undergo oral examination on days 0, 7, 14, 21, and 28 to evaluate the severity of the mucositis (according to World Health Organization scale). Immediately after occurrence of grade 1 mucositis, in addition to using Achillea wilhelmsii mouthwash, patients will use Magic mouthwash, which is a common treatment for oral mucositis due to cancer treatment.
Category
Treatment - Drugs

2

Description
Control group: From the first day of cancer treatment, the control group will use placebo mouthwash. Normal saline solution produced by Shahid Ghazi Pharmaceutical Company of Tabriz will be used as a placebo. Patients should hold 15 ml of the prescribed mouthwash in their mouth for 3 minutes 4 times a day (after each meal and before bed) and then expel it. Patients will undergo oral examination on days 0, 7, 14, 21, and 28 to evaluate the severity of the mucositis (according to World Health Organization scale). Immediately after occurrence of grade 1 mucositis, in addition to using placebo mouthwash, patients will use Magic mouthwash, which is a common treatment for oral mucositis due to cancer treatment.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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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
Zanjan 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
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Dr. Raheleh Akhavan Rasoolzadeh
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Person responsible for updating data

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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

Not applicable