

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Efficacy of the Malva sylvestris & Alcea digitata compound on prevention of radiation induced acute mucositis in head and neck cancer patients

Protocol summary

Summary

Objectives: Evaluating the efficacy of Malva sylvestris & Alcea digitata compound on prevention of radiation induced acute mucositis (OM) in head and neck cancer patients Design: Randomized, double-blind, placebo-controlled clinical trial Setting & Conduct: The study will be performed in one center and will include A herbal drug group and A placebo group. Each group will consist of 22 Head&Neck cancer patients with Radiotherapy (RT). Major Inclusion criteria: patients with 17-65 years old in both sexes; candidate for radiotherapy for head & neck cancers; life expectancy over 1 year; Good performance status in ECOG questionnaire; At least 4 areas in RT fields Major Exclusion criteria: Patients with organic & suppressive disorders; Use of drugs effective on salivary glands, cigar or alcohol; History of RT in last 6 months; Grade 3-4 Mucositis, candidiasis, oral herpes; Failure to treat, Hospitalization or need to TPN; Lack of interest in work Intervention: Seven week administration of herbal drug or placebo (Avecil) sachets, will be conducted, 3 times a day. During the 7 weeks study, follow-up observations of primary and secondary outcomes will be performed. Main outcome measures: The primary outcomes is presence/ absence and grade of OM, Severity of mouth pain on the visual analogue scale and OM-related quality of life on EORTC questionnaire. Secondary outcomes are side effects of drug and placebo. All outcomes will be measured at baseline, at each week of study to 2 weeks after RT.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120520208N1**

Registration date: **2015-09-29, 1394/07/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-29, 1394/07/07

Registrant information

Name

Nasser Rezaeipour

Name of organization / entity

Medical Faculty of Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 7728 6873

Email address

n.rezaeipour@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahed University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of the Malva sylvestris & Alcea digitata compound on prevention of radiation induced acute mucositis in head and neck cancer patients

Public title

Efficacy of the Malva sylvestris & Alcea digitata compound on prevention of radiation induced acute

mucositis in head and neck cancer patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with 17-65 years old in both sexes; candidate for radiotherapy for head & neck cancers; life expectancy over 1 year; Good performance status in ECOG questionnaire; At least 4 areas in RT fields
Early Exclusion criteria: Patients with organic & suppressive disorders; Use of drugs effective on salivary glands, cigar or alcohol; History of Rt in last 6 months; Grade 3-4 Mucositis, candidiasis, oral herpes; Failure to treat, Hospitalization or need to TPN; Lack of interest in work

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Patients will be divided to two groups with stratification form based at performance status, age (less and equal 50 and over 50 years old), and probable Simultaneous chemotherapy.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahed University of Medical Sciences

Street address

Abdolahzadeh Ave. Keshavarz Boulevard

City

Tehran

Postal code

Approval date

2014-11-22, 1393/09/01

Ethics committee reference number

41/215586

Health conditions studied

1

Description of health condition studied

Mucositis

ICD-10 code

K12.3

ICD-10 code description

Oral mucositis (ulcerative)

Primary outcomes

1

Description

Mucositis

Timepoint

At the baseline, Weeks 1,2,3,4,5,6,7

Method of measurement

Examination of Oral Cavity

2

Description

Pain

Timepoint

At the baseline, Weeks 1,2,3,4,5,6,7

Method of measurement

Visual Analogue Scale

3

Description

Quality of Life

Timepoint

Weeks 1,2,3,4,5,6,7

Method of measurement

EORTC questionnaire

Secondary outcomes

1

Description

Side Effects

Timepoint

Weeks 1,2,3,4,5,6,7

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group 1: 4 gram Sachets of Malva sylvestris & Alcea digitata compound (2 grams of each Herb); For 7 weeks; 3 times daily after meals

Category

Treatment - Drugs

2

Description

Control Group: 4 gram Sachets of Avecil; For 7 weeks; 3 times a day, after meals

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Ahmad Ameri

Street address

Shahid Madani St., Nezam Abad, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahed University

Full name of responsible person

Zahra Kiasalari

Street address

Opposite Imam Khomeini's Spulcher, Khalije Fars Exp Way

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Shahed University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahed University of Medical Sciences

Full name of responsible person

Nasser Rezaeipour

Position

PhD Student of Traditional Iranian Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Nasser Rezaeipour, MD

Position

PhD Student of Traditional Iranian Medicine

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty