Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparative evaluation of efficacy of the Malva sylvestris and Alcea digitata formulation with Hypozalix (artificial saliva) in the radiation induced xerostomia and quality of life in patients with head– and– neck cancers

Protocol summary

Summary

The goal of this randomized, single-center, phase II clinical trial study, is comparative evaluation of efficacy of the Malva sylvestris and Alcea digitata formulation with Hypozalix (artificial saliva) in the radiation induced xerostomia and quality of life in patients with head and neck cancers. Inclusion criteria are: a minimum of 20 and maximum age of 70 years old; having xerostomia at least grade 1 based on clinical grading CTC; adverse event 4, and at least three months after the end of radiotherapy. Exclusion criteria: sudden changes in systemic conditions like that a patient requires extensive chemotherapy and surgical interventions, Failure / need parenteral nutrition (TPN) or hospitalization and unwillingness to continue participation in the study. Patients with a sample size of 60 persons in both two groups, enter the study. Intervention: Malva sylvestris and Alcea digitata formulation and Hypozalix (both three times daily) are given to patients for 4 weeks. Finally xerostomia and quality of life are measured by VAS scale, questionnaire and examination.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012415860N1**
Registration date: **2014-01-24, 1392/11/04**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-01-24, 1392/11/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of efficacy of the Malva sylvestris and Alcea digitata formulation with Hypozalix (artificial saliva) in the radiation induced xerostomia and quality of life in patients with head– and– neck cancers

Public title

Comparative evaluation of efficacy of the Malva sylvestris and Alcea digitata formulation with an artificial

saliva in the radiation induced xerostomia and quality of life in patients with head– and– neck cancers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: xerostomia at least grade 1 based on clinical grading CTC; adverse event 4; age between 20 to 70 years old; physically and mentally able to fill out a questionnaire; willingness to participate in the study and informed consent; at least three months after the end of radiotherapy; not drinking alcohol; drugs affecting the salivary glands like antidepressant, opioids, antihypertensive, antihistamines, diuretics, all kind of mouthwash and artificial saliva; no history of connective tissue disease like Sjogren, rheumatoid arthritis, lupus, liver disease, kidney disease, major depression, diseases involving salivary glands, diabetes, chronic diseases such as diarrhea cause dehydration; the absence ofneutropenia, immunosuppression, myelosuppression Exclusion criteria: sudden changes in systemic conditions like that a patient requires extensive chemotherapy and surgical interventions; failure/ need parenteral nutrition (TPN) or hospitalization; unwillingness to continue participation in the study.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Office of Research Affairs, Deputy of Research and Technology, Shahid Beheshti University of Medical

Street address

Sixth Floor, College Staff Building Number Two, Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Parvaneh St., Yemen St., Shahid Chamran Highway.

City

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Postal code

Approval date

2013-12-01, 1392/09/10

Ethics committee reference number

143

Health conditions studied

1

Description of health condition studied

Radiation induced xerostomia

ICD-10 code

K11.7

ICD-10 code description

Dry mouth, unspecified

Primary outcomes

1

Description

Xerostomia

Timepoint

Before interventin & weeks 2 and 4 after intervention

Method of measurement

VAS scale (determined by Question from patient) & Xerostomia Grade (determined by clinical examination)

2

Description

Quality of life

Timepoint

Before interventin and 4 weeks after intervention.

Method of measurement

EORTC questionnaire

Secondary outcomes

1

Description

Other Symptoms

Timepoint

Before interventin and 4 weeks after intervention.

Method of measurement

Question from patient

Intervention groups

1

Description

Intervention group 1: Hypozalix 100 mL artificial saliva sprays, three times a day, every time two puffs, for 4 weeks.

Category

Treatment - Drugs

2

Description
Intervention group 2: Sachets of Malva sylvestris and Alcea digitata formulation, three times a day, each time one sachet into a cup of boiling water, stirred, and after cooling, drink it. For 4 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Radiation Oncology, Imam Hossein Hospital, Shahid Beheshti University of Medical Scien
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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No.8 Shams Alley, opposite St tavanir, Vali Asr Street, Tehran
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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
School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center,Shahid Behes
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

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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