Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

Summary

The goal of this randomized clinical trial study, is assessment of efficacy of the Malva sylvestris & Alcea digitata & Plantago Psyllium compound on prevention of radiation induced xerostomia in head and neck cancer patients. Inclusion criteria are: head and neck cancer patients who candidate for radiation therapy, with a minimum of 17 and maximum age of 65 years old, having Good Performance status according with ECOG questionnaire criteria, having at least 4 regions of mucositis (based on a measure of mucositis) in the field of radiation therapy. Exclusion criteria: grade 3 & 4 mucositis, candidiasis and oral herpes infection, sudden changes in the patient's condition or disease in which changing the predicted radiation procedure for patient before getting to dose of 50 Gy, failure / need parenteral nutrition (TPN) or hospitalization and unwillingness to continue participation in the study. Patients with a sample size of 44 persons in both two groups, enter the study. Intervention: experimental group received the Malva sylvestris & Alcea digitata compound and "standard protocol of care", and the control group received placebo and "health care standard protocol". Duration of intervention is started at the beginning of the radiation therapy and continued till 2 weeks after finishing radiation therapy. Xerostomia and quality of life are measured by VAS scale, questionnaire and examination before intervention, 2 and 6 weeks after finishing radiation therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091015860N3**
Registration date: **2015-09-17, 1394/06/26**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-09-17, 1394/06/26

Registrant information

Name

Ghazaleh Heydarirad

Name of organization / entity

School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center, Shahid Behe

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-09-16, 1394/06/25

Expected recruitment end date

2016-03-15, 1394/12/25

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 xerostomia in head and neck cancer patients

Public title

Efficacy of the Malva sylvestris & Alcea digitata &Plantago Psyllium on prevention of radiation induced

xerostomia in head and neck cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria include: 1. head and neck cancer patients who candidate for radiation therapy 2. minimum age of 17 and maximum age of 65 years old 3. having Good Performance status according with ECOG questionnaire criteria 4. having at least 4 regions of mucositis (based on a measure of mucositis) in the field of radiation therapy 5. physically and mentally able to fill out a questionnaire 6. willingness to participate in the study 7. survival more than one year according to the oncologist or treatment team. Exclusion criteria:The use of alcohol, medicines which affecting the salivary glands such as: anti-depression, opioids, anti-hypertensive, antihistamines, diuretics, types of mouthwash and artificial saliva and smoking during the study; Receiving radiation therapy and chemotherapy in the mouth and oropharynx in the six months ago; The history of connective tissue diseases such as Sjogren's syndrome, rheumatoid arthritis, lupus, liver and kidney disease, major depression, diseases involving salivary glands, diabetes, chronic diseases such as diarrhea cause dehydration, immune suppression disorders, myelosuppression, disorders which causing frequent aphthous stomatitis; Sudden changes in the patient's condition or disease in which changing the predicted radiation procedure for patient before getting to dose of 50 Gy; Grade 3 & 4 mucositis; Candidiasis and oral herpes infection; Failure/ need parenteral nutrition (TPN) or hospitalization; Unwillingness to continue participation in the study

Age

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

Gender

Both

Phase

2

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Keshavarz boulevard, Tehran University of Medical Sciences, Tehran

City

Tehran

Postal code

Approval date

2015-03-04, 1393/12/13

Ethics committee reference number

27838

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 and 2 and 6 weeks after finishing radiation therapy

Method of measurement

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

Secondary outcomes

1

Description

Quality of life

Timepoint

Before interventin and 2 and 6 weeks after finishing radiation therapy

Method of measurement

EORTC questionnaire

Intervention groups

1

Description

In the exprimental group: Malva sylvestris & Alcea digitata & Plantago Psyllium compound and "health care standard protocol", starting at begining of radiation therapy and will continue up to 2 weeks after finishing radiation therapy, three times a day.

Category
Treatment - Drugs

2

Description
In the control group, placebo and "health care standard protocol", starting at begining of radiation therapy and will continue up to 2 weeks after finishing radiation therapy, three times a day.
Category
Placebo

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
Ahmad Ameri,M.D, Board of specialists in Radiation - Oncology, Associate Professorl
Street address
Imam Hossein Hospital, Nezam Abad, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Hossein Rezaeizade
Street address
Faculty of Traditional Medicine, west. Jamali, Vafamanesh st., Heravi sq., Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
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
Tehran University of Medical Sciences
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Ghazaleh Heydarirad
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Person responsible for updating data

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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