Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of Mucosamin in treatment of radiation induced oral cavity mucositis during and after radiotherapy، in patient with oral cavity squamous cell carcinoma (SCC)

Protocol summary

Study aim
Evaluation of the effect of Mucosamin in the treatment of oral cavity mucositis during and after radiotherapy in patients with oral cavity squamous cell carcinoma

Design
This study is a phase II randomized clinical trial. Participants were randomly divided into two groups according to the random number table: intervention group = 40 people; control group = 40 people

Settings and conduct
This study will be conducted after approval by the ethics committee of Shiraz University of Medical Sciences and all patient information will remain confidential. The checklist will include demographic information (age, sex), complete medical and surgical history, physical examination, and clinical condition. Patients with oral cavity squamous cell carcinoma with pathologic diagnosis are exposed to radiation of at least 6000 cGy. Oral mucositis and pain severity are recorded weekly during treatment and in the first and second weeks after radiation therapy. The phone number and address of all patients will be obtained to contact them if they do not visit for follow-up.

Participants/Inclusion and exclusion criteria
Inclusion criteria include people aged 18-75 years; patients with non-metastatic oral cavity squamous cell carcinoma with oral mucositis induced by radiation; performance status <= 2. Exclusion criteria include people younger than 18 or over 75 years; patients with systemic disease affecting wound healing (diabetes); muco-cutaneous diseases; poor oral hygiene; previous head and neck surgery; radiotherapy and chemotherapy due to malignancy; distant metastases at the time of diagnosis.

Intervention groups
Intervention group: taking Mucosamin spray for 3-4 times a day; Control group: taking the mixing aluminum or magnesium hydroxide, diphenhydramine and nystatin 3 times a day.

Main outcome variables
Oral mucositis; severity of pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190511043551N1**
Registration date: **2019-10-16, 1398/07/24**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-16, 1398/07/24**
Update count: **0**

Registration date
2019-10-16, 1398/07/24

Registrant information

Name
Saeedeh Khaki

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3224 1316

Email address
khaki@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-02, 1398/07/10

Expected recruitment end date
2019-12-31, 1398/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Mucosamin in treatment of radiation induced oral cavity mucositis during and after radiotherapy، in patient with oral cavity squamous cell carcinoma (SCC)

Public title

Mucosamin in treatment of oral cavity mucositis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Non-metastatic oral cavity squamous cell carcinoma with oral mucositis induced by radiation People aged 18-75 years

Exclusion criteria:

Patients with systemic disease which impairs wound healing (diabetes) Muco-cutaneous disease Poor oral hygiene

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this trial, subjects will be randomly assigned to one of two intervention and control groups using the random number table. There are no prerequisites for assigning individuals to groups. The randomization unit is individual. Each participant will have an equal chance of being placed in each group.

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

Ethics committee of Shiraz University of Medical Sciences

Street address

Faculty of medicine, Zand avenue

City

Shiraz

Province

Fars

Postal code

71937-11351

Approval date

2019-03-09, 1397/12/18

Ethics committee reference number

IR.SUMS.MED.REC.1397.473

Health conditions studied

1

Description of health condition studied

Radiation-induced Mucositis in patients with Oral cavity Squamous Cell Carcinoma

ICD-10 code

C00-C14

ICD-10 code description

Malignant neoplasms of lip, oral cavity and pharynx

Primary outcomes

1

Description

The degree of oral cavity mucositis induced by Radiotherapy

Timepoint

Oral cavity examination weekly from the first week of radiotherapy to two weeks after the radiotherapy

Method of measurement

Oral Mucositis Oncology Radiotherapy Group Scoring Table

Secondary outcomes

1

Description

Severity of pain

Timepoint

Weekly patient visit from the first week of radiotherapy to two weeks after the radiotherapy

Method of measurement

Patient's history and complaint

Intervention groups

1

Description

Intervention group: taking mucosamin spray for 3-4 times/day

Category
Treatment - Drugs

2

Description
Control group: taking standard treatment (magnesium-aluminium-hydroxide, diphenhydramine and nystatin) for 3 times/day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi hospital
Full name of responsible person
Hamid Nasrollahi
Street address
Radiation Oncology Department, Namazi hospital, Namazi square
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nasrolahih@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Qasemi
Street address
Zand Blvd, Shiraz University of Medical Sciences
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vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Arena Life Science Company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Saeedeh khaki
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The checklist will include demographic information (age, sex), complete medical and surgical history, physical examination, and clinical disease conditions for each patient. The oral mucositis oncology radiotherapy scoring table will be filled for each patient. At the end of the study this information can be shared

When the data will become available and for how long
Start of access period 6 months after printing results

To whom data/document is available
Researchers working in academia and people in the industry.

Under which criteria data/document could be used
To continue investigations in this field and similar fields by other researchers and For comparison as a control group in similar studies

From where data/document is obtainable
saeede_khaki@yahoo.com Saeedeh Khaki Namazi Hospital, Shiraz, Radiotherapy Department 07136125367

What processes are involved for a request to access data/document
Send the research project to the following email address saeede_khaki@yahoo.com

Comments