Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of aloe vera mouthwash and and Benzydamine Hydrochloride mouthwash on radiation induced mucositis in patients with head and neck cancer

Protocol summary

Summary

Study objective: The main objective of the project: Comparative evaluation of the effects of Aloe Vera and Benzydamine HCL mouth rinses on the mucositis caused by radiotherapy in patients with head and neck cancer. The secondary objectives: Effect of Aloe Vera mouth rinse on Mucositis grade, effect of Benzydamine HCL mouth rinse on Mucositis grade, comparing the effects of Aloe Vera and Benzydamine HCL mouth rinses on Mucositis grade- Design of study: randomized, triple blind, without placebo, single-Center, Phase II trial- study population: main inclusion criteria: Minimum age of 18 years, diagnosed cancer in the head and neck region, the minimum therapeutic dose of 50 Gy, oral cavity is placed in the radiation field- main exclusion criteria: history of cancer treatment during last year, history of food allergy, presence of any oral lesions including active infection, oral ulcers before starting radiation therapy- Target sample size: 26 people- study Intervention: Patients are divided into two groups by balanced block randomization. Two types of drugs are being used in this study: 1 - Aloe Vera Mouth rinse (%100) 2 - Benzydamine hydrochloride Mouth rinse(0 .15 %) (common palliative treatment of mucositis) Patients are asked to use mouthwash , three times daily, during the six weeks period of the Radiotherapy and even one week more after it. To investigate the effects of drugs on the degree of mucositis, the table provided by the World Health Organization (WHO) is used. Expected recruitment start date:10/7/2012- Expected recruitment end date: 9/1/2013- Study primary outcome: Mucositis grade

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012072410377N1**

Registration date: **2012-11-16, 1391/08/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-16, 1391/08/26

Registrant information

Name

Mohammad Haji Mirza Mohammad

Name of organization / entity

Oral medicine department, school of Dentistry Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4428 0101

Email address

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Recruitment status

Recruitment complete

Funding source

Pharmaceutical Company Barij Essence, vice chancellor for research, school of Dentistry Tehran University of Medical Sciences

Expected recruitment start date

2012-07-10, 1391/04/20

Expected recruitment end date

2013-01-09, 1391/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of aloe vera mouthwash and and Benzydamine Hydrochloride mouthwash on radiation induced mucositis in patients with head and neck cancer

Public title
Comparison the effect of Aloe Vera and Benzydamine hydrochloride mouth rinses on mucositis caused by radiation

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Minimum age: 18 years, diagnosed cancer in the head and neck region, the minimum therapeutic dose of 50 Gy, oral cavity is placed in the radiation field, the patient's ability to cooperate and use medications as directed. Exclusion criteria: Patients with a history of cancer treatment during the last year, patients with a history of food allergy, oral lesions including active infection, mouth ulcers before starting the radiation therapy, lack of patient willingness and cooperation to participate in the study.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **26**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Process of randomization: Pharmaceutical Company " Barij Essence" will be packaged the mouth rinses into two quite similar bottles and will be send them to School of Dentistry, Tehran University of Medical Sciences. Two non-beneficiaries will label the bottles and then will give them to the Researcher. Without being aware about the mouth rinses ingredients, and just based on the ordering (numbers) The researcher will give the bottles to the patients. Patients will not aware about the content of the rinses either. In the consent form it is indicated that Rinses contain Benzydamine or Aloe Vera extract. Neither the researcher, nor the patients nor the statistical analyzer will be aware of the type of mouth rinses.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice chancellor for research,Tehran University of Medical Sciences

Street address
The Sixth Floor, central Organization of University, Keshavarz Blvd.

City
Tehran

Postal code

Approval date
2012-07-23, 1391/05/02

Ethics committee reference number
91\130\926\ص

Health conditions studied

1

Description of health condition studied
Mucositis

ICD-10 code
L58.0

ICD-10 code description
Acute radio dermatitis

Primary outcomes

1

Description
Mucositis grade

Timepoint
From Starting of radiation therapy, weekly during 6 weeks of treatment and 1 week after treatment

Method of measurement
questionnaire based on the Mucositis grade rating items from the World Health Organization (WHO)

Secondary outcomes

1

Description
mouth soreness

Timepoint
From starting of radiation therapy, weekly during 6 weeks of treatment and 1 week after treatment

Method of measurement
Questionnaire (Asking from patient)

2

Description
Ulcer

Timepoint
From starting of radiation therapy, weekly during 6

weeks of treatment and 1 week after treatment

Method of measurement

Questionnaire (Observation)

3

Description

Disability to swallowing solid food

Timepoint

From starting of radiation therapy, weekly during 6 weeks of treatment and 1 week after treatment

Method of measurement

Questionnaire (Asking from patient)

4

Description

Disability to alimentation

Timepoint

From starting of radiation therapy, weekly during 6 weeks of treatment and 1 week after treatment

Method of measurement

Questionnaire (Asking from patient)

5

Description

Erythema

Timepoint

From starting of radiation therapy, weekly during 6 weeks of treatment and 1 week after treatment

Method of measurement

Questionnaire (Asking from patient and observation)

Intervention groups

1

Description

Intervention: Aloe vera mouth rinse, chemical composition: Aloe vera gel 100%, concentration of 0.0009% Blue color Brilliant Blue, concentration of 0.0006% yellow color Tarterazine, manufacturer: Baryj Essence Pharmaceutical Company- During 6 weeks of Radiotherapy and up to 1 week after it, patients are asked to use 5 cc of mouth rinse 3 times a day, each time for 2 minutes and are avoid from eating and drinking for 30 minutes after using the mouth rinse.

Category

Prevention

2

Description

Control: Benzydamine hydrochloride Mouth rinse, chemical composition: Benzydamine hydrochloride 0/15 %, manufacturer: pharmaceutical company Behvazan, brand: Behvazan 0/15% - During 6 weeks of Radiotherapy and up to 1 week after it, patients are asked to use 5 cc of mouth rinse 3 times a day, each time for 2 minutes and are avoid from eating and drinking for 30 minutes after using the mouth rinse.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Institute of Imam Khomeini Hospital of Tehran University of Medical Sciences

Full name of responsible person

Dr Ali Kazemian

Street address

Room Number 3, radiotherapy Clinic, cancer Institute, Imam Khomeini Hospital, Keshavarz Blvd, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baryj Essence Pharmaceutical Company

Full name of responsible person

Doctor Mohsen Taghizadeh

Street address

Department of Biochemistry and Nutrition, Kashan University of Medical Sciences, Kashan, I.R.Iran.

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Baryj Essence Pharmaceutical Company

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Vice chancellor for research, school of Dentistry Tehran University of Medical Sciences

Full name of responsible person

Tahereh Sadat Jafarzadeh Kashi

Street address

Vice chancellor for research, second floor, school of Dentistry Tehran University of Medical Sciences, next

to nuclear energy Organization, North kargar Street, Tehran

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, school of Dentistry Tehran University of Medical Sciences

Proportion provided by this source

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
School of Dentistry Tehran University of Medical Sciences, oral medicine Department

Full name of responsible person
Doctor Arash Mansourian

Position
Associated Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Doctor Mahnaz Saheb Jamee

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Professor/DDS.MS

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Person responsible for updating data

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Full name of responsible person
Mohammad Haji Mirza Mohammad

Position
Resident of oral medicine

Other areas of specialty/work

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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