Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of Bene (Pistacia atlantica) oleoresin mouthwash for prevention of chemotherapy-induced oral mucositis

Protocol summary

Study aim
Evaluation of Bene mouthwash for prevention of chemotherapy-induced oral mucositis

Design
A placebo-controlled parallel-group triple-blind randomized clinical trial

Settings and conduct
The clinical trial will be conducted at the Firoozgar Hospital, and eligible patients admitting to the blood ward for chemotherapy will be recruited. Pre-coded randomized placebo and drug mouthwashes will be delivered to the subjects. The severity of oral mucositis will be assessed using the World Health Organization grading system and a questionnaire at baseline and on days 21, 14, 7, 3 after the intervention. Patients, healthcare providers, and the data analyzer will all be blind in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) age 18 to75 years 2) isn't first cycle of chemotherapy 3)receipt of at least two cytotoxic drugs 4)a treatment regimen containing 5-fluorouracil 5) history of mucositis or any oral complications due to chemotherapy 6) absence of mucositis at recruitment 7) performance status grade of less than or equal to two according to the Eastern Cooperative Oncology Group (ECOG) scale. Exclusion criteria: 1) simultaneous radiotherapy in head and neck 2) pregnancy and lactation 3) allergic reaction.

Intervention groups
Two parallel groups; one receives Bene mouthwash while the other is given the placebo

Main outcome variables
Severity of the oral mucositis based on the World Health Organization grading system; soreness or pain in the mouth; trouble with talking and swallowing; blood and feeling of dryness in the mouth

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191023045223N1**
Registration date: **2020-07-29, 1399/05/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-29, 1399/05/08**
Update count: **0**

Registration date
2020-07-29, 1399/05/08

Registrant information
Name
Atefe Fathi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-12-22, 1398/10/01
Expected recruitment end date
2020-12-20, 1399/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Evaluation of Bene (Pistacia atlantica) oleoresin mouthwash for prevention of chemotherapy-induced oral mucositis

Public title
Bene mouthwash for prevention of chemotherapy-induced oral mucositis
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 75 years isn't first course chemotherapy Receipt of at least two cytotoxic drugs; a treatment tment regimen containing 5-fluorouracil (5fu); history of mucositis, dryness, or any oral complications in the previous courses of chemotherapy; absence of oral mucositis at the beginning of the study; performance status grade of less than or equal to two according to the Eastern Cooperative Oncology Group (ECOG) scale
Exclusion criteria:
Simultaneous radiotherapy in head and neck; sensitivity to the Pistacia atlantica; pregnancy and lactation
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The blockchain randomization is employed and random number table is used as the randomization tool.
Blinding (investigator's opinion)
Triple blinded
Blinding description
A person not involved in the study will code the mouthwashes and the coded mouthwashes will be given to the patients. The participants, the researcher, the data analyst, and the healthcare providers involving the physician and the nurses will not be aware of the codes.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethis committee of Islamic Azad University of Tehran Medical Sciences
Street address
Yakhchal st., Gholhak st., Dr. Shariati st.
City
tehran
Province
Tehran
Postal code
1941933111
Approval date
2019-09-02, 1398/06/11
Ethics committee reference number
IR.IAU.TMU.REC.1398.110

Health conditions studied

1

Description of health condition studied
oral mucositis
ICD-10 code
K12.31
ICD-10 code description
Oral mucositis (ulcerative) due to antineoplastic therapy

Primary outcomes

1

Description
The severity of the oral mucositis according to the World Health Organization grading system
Timepoint
Baseline and 3, 7, 14, 21 days after the intervention
Method of measurement
The World Health Organization Grading System

2

Description
Soreness or pain in the mouth
Timepoint
Baseline and 3, 7, 14, 21 days after the intervention
Method of measurement
Patient-reported outcomes based on scoring 0 to 10

3

Description
Trouble with talking
Timepoint
Baseline and 3, 7, 14, 21 days after the intervention
Method of measurement
Patient-reported outcomes based on scoring 0 to 10

4

Description
Trouble with eating solid foods (such as bread)
Timepoint
Baseline and 3, 7, 14, 21 days after the intervention
Method of measurement
Patient-reported outcomes based on scoring 0 to 10

5

Description
Trouble with eating soft foods (such as yogurt and baked potatoes)
Timepoint
Baseline and 3, 7, 14, 21 days after the intervention
Method of measurement
Patient-reported outcomes based on scoring 0 to 10

6

Description
Difficulty in swallowing due to the sore throat
Timepoint
Baseline and 3, 7, 14, 21 days after the intervention
Method of measurement
Patient-reported outcomes based on scoring 0 to 10

7

Description
Taste changes
Timepoint
Baseline and 3, 7, 14, 21 days after the intervention
Method of measurement
Patient-reported outcomes based on scoring 0 to 10

8

Description
Bleeding or sore gums
Timepoint
Baseline and 3, 7, 14, 21 days after the intervention
Method of measurement
Patient-reported outcomes based on scoring 0 to 10

Secondary outcomes

1

Description
Feeling of dryness in the mouth
Timepoint
Baseline and 3, 7, 14, 21 days after the intervention
Method of measurement
Patient-reported outcomes based on scoring 0 to 10

Intervention groups

1

Description
Intervention group: receiving Bene oleoresin 1% mouthwash to be used twice daily for a week
Category
Prevention

2

Description
Control group: receiving placebo (absence of Bene oleoresin) to be applied twice daily for a week
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Dr. Mehdi Rajabi
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Firouzgar Hospital, behafarin Ave, karim khan Ave, Valiasr Sq.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Mehdi Rajabi
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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
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Atefe Fathi
Position
Pharmacist
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Bene mouthwash for prevention of the chemotherapy-induced oral mucositis
When the data will become available and for how long

6 months after publication

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Full description of the intended analyses and the applications

From where data/document is obtainable

Dr. Atefeh Fathi, E-mail: a.fathi2696@gmail.com

What processes are involved for a request to access data/document

If the request was accepted, the data would be sent to the applicant as soon as possible

Comments