Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

The effect of oral rinse Peppermint Essence (PE) in prevention of chemotherapy- induced oral mucositis

Protocol summary

Summary

Purpose: This study has been conducted to determine the effect of using oral rinse Peppermint Essence (PE) in prevention of chemotherapy-induced oral mucositis (OM). Materials & Methods: 40 patients with colon & rectum cancer, who admitted for chemotherapeutic management, were enrolled in a double blind clinical trial and they randomly divided in two equal, placebo & PE groups. They had to receive 10 drop of oral rinse PE or placebo, tree times a day, from the first day of chemotherapy up to the fourteenth day. Data tools included a bipartite questionnaire (demographic Q & clinical Q) and World Health Organization (WHO) scale for measurement of OM.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809222846N1**
Registration date: **2010-05-19, 1389/02/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-05-19, 1389/02/29

Registrant information

Name

Tahereh Ashktorab

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 1543

Email address

t_ashktorab@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Private

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2009-12-11, 1388/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral rinse Peppermint Essence (PE) in prevention of chemotherapy- induced oral mucositis

Public title

The effect of oral rinse Peppermint Essence (PE) in prevention of chemotherapy- induced oral mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: consciousness/literate/ admitted to hospital with colon or rectum cancer/ chemotherapeutic management with 5-fluorouracil / no stomatitis/ no oral disease/ no asthma/ no renal & liver disorders/ no auto immune disease and diabetes/ no fever and neutropenia/ no recieved antibiotic & narcotic analgesic/ no recieved another oral rinse /no mint family allergy.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked
No information
Sample size
Target sample size: **40**
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
The International Branch of Shahid Beheshti University of Medical Sciences
Street address
No. 19, Shaheed Abbas pour, Vali Asr
City
Tehran
Postal code
14155-3693
Approval date
2009-09-20, 1388/06/29
Ethics committee reference number
116/677

Health conditions studied

1

Description of health condition studied
oral mucositis
ICD-10 code
K13
ICD-10 code description
Other diseases of lip and oral mucosa

Primary outcomes

1

Description
oral mucositis
Timepoint
daily
Method of measurement
observation with a check list

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: 10 drops of oral rinse Peppermint Essence, tree times a day, from the first day of chemotherapy up to the fourteenth day
Category
Prevention

2

Description
Control: placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tajrish hospital
Full name of responsible person
Street address
City
Tehran

2

Recruitment center
Name of recruitment center
Emam Hosein hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Researcher
Full name of responsible person
Tahereh Ashktorab
Street address
Faculty of Nursing, Shahid Beheshti University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Researcher

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

Faculty of nursing , Shahid Beheshti University of Medical Sciences

Full name of responsible person

Tahereh Ashktorab

Position

PhD

Other areas of specialty/work

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Person responsible for updating data

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Zahra Yazdani

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yazdani_za@yahoo.com

Web page address

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