

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

t_ashktorab@sbmu.ac.ir

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.

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

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

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
Street address
Faculty of nursing , Shahid Beheshti University of
Medical Sciences, Shariati street
City
Tehran
Postal code
Phone
+98 21 2222 1543
Fax
Email
t_ashktorab@sbmu.ac.ir
Web page address

Person responsible for scientific 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
Street address
Faculty of nursing of Shahid Beheshti University of
Medical Sciences, Shariati street
City
Tehran
Postal code
Phone
+98 21 2222 1543
Fax
Email
t_ashktorab@sbmu.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Faculty of nursing , Shahid Beheshti University of
Medical Sciences
Full name of responsible person
Zahra Yazdani
Position
Other areas of specialty/work
Street address
City
Postal code
Phone
Fax
Email
yazdani_z@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