Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of Calendula officinalis extract on radiotherapy-induced oral mucositis

Protocol summary

Summary

The aim of present study was to investigate the effect of Calendula officinalis extract on radio-therapy induced oral mucositis. This non-randomized double blind clinical trial was conducted on individuals newly diagnosed of head and cancers. 40 patients with radio-therapy treatment plan with at least 40 Gray exposure doses to oral filed according to the treatment protocol and minimum age of 45 were selected and divided into two equal numbered groups of case and control. Each group of case and control was divided into two groups of male and female. Tumor sites were matched in all groups. Exclusion criteria were pregnancy, allergy to mouthwashes, preexisting oral conditions, use of other medications related to oral mucositis during study period, any systemic diseases interfering with healing. From onset of radio-therapy, patients were given either placebo or 2% Calendula mouthwashes, three times daily for 6 weeks. Each time patients held 5 ml of mouthwash in oral cavity for 1 minute and then spitted it out. At the end of each week, oral mucositis intensity was measured by Oral Mucositis Assessment Scale (OMAS), which is based on the scores of erythema and ulcer in 9 areas of oral cavity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106076734N1**
Registration date: **2011-06-13, 1390/03/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-06-13, 1390/03/23

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of research for Babol University of Medical Sciences

Expected recruitment start date

2008-02-20, 1386/12/01

Expected recruitment end date

2009-04-21, 1388/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of Calendula officinalis extract on radiotherapy-induced oral mucositis

Public title

Investigation of Calendula officinalis extract on radiotherapy-induced oral mucositis

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: 1) Minimum accumulative dose of 40 Gy according to treatment protocol; 2) Complete

exposure of oral field to x ray; 3) Minimum age of 45; Exclusion criteria were: 1) Pregnancy; 2) Allergy to the mouthwash; 3) Preexisting oral conditions; 4) Use of other medications related to oral mucositis during study period; 5) Any systemic diseases interfering with healing

Age
From **45 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Not 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
Ethics committee of Babol University of Medical Sciences

Street address
Babol University of Medical Sciences, Ganj Afrooz Str

City
Babol

Postal code

Approval date
2008-03-18, 1386/12/28

Ethics committee reference number
10124

Health conditions studied

1

Description of health condition studied
Oral Mucositis

ICD-10 code
K13.7

ICD-10 code description
Other and unspecified lesions of oral mucosa

Primary outcomes

1

Description
Intensity of oral mucositis

Timepoint
at the end of each week for total of 6 weeks for each patient

Method of measurement
Oral Mucositis Assessment Scale (OMAS)

Secondary outcomes

empty

Intervention groups

1

Description
A gel which was equalized in taste, odor, shape and color to 2% Calendula mouthwash was used as a placebo mouthwash. Patients were instructed to use the mouthwash 3 three times daily from onset of radio-therapy for 6 week duration. Each time patients held 5 ml of mouthwash in their oral cavity for 1 minute.

Category
Placebo

2

Description
Herbal extract of plant Calendula officinalis was added to a basic gel to make 2% calendula mouthwash. Patients were instructed to use the mouthwash 3 three times daily from onset of radio-therapy for 6 week duration, each time patients held 5 ml of mouthwash in their oral cavity for 1 minute and then spitted it out.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Radiotherapy centre of Shahid Rajaie hospital of Babolsar

Full name of responsible person
Neda Babaee

Street address
Sahid Rajaie hospital, next to Shilat, Shariatie Str, Babolsar

City
Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Babol University of Medical Sciences
Full name of responsible person
Amrollah Mostafazadeh
Street address
Babol University of Medical Sciences
City
Babol
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, Babol University of Medical Sciences
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

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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