

# 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

##### Name

Neda Babaei

##### Name of organization / entity

Department of oral diseases, Dental school of Babol  
University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 1223 4650

##### Email address

n.babaei@mubabol.ac.ir

#### 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

**Contact****Name of organization / entity**

Department of oral diseases, Dental School of Babol University of Medical Sciences

**Full name of responsible person**

Neda Babaee

**Position**

Assistant professor, DDS, MS

**Other areas of specialty/work****Street address**

Department of oral diseases, Dental School of Babol University of Medical Sciences, Felestin Str, Velayat Square

**City**

Babol

**Postal code****Phone**

+98 11122914089

**Fax****Email**

n.babaee@mubabol.ac.ir;  
dr\_nedababaee@yahoo.com

**Web page address**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Department of oral diseases, Dental School of Babol University of Medical Sciences

**Full name of responsible person**

Neda Babaee

**Position**

Assistant professor, DDS, MS

**Other areas of specialty/work****Street address**

Department of oral diseases, Dental School of Babol University of Medical Sciences, Felestin Str, Velayat square

**City**

Babol

**Postal code**

853

**Phone**

+98 11122914089

**Fax****Email**

n.babaee@mubabol.ac.ir;  
dr\_nedababaee@yahoo.com

**Web page address**

### Person responsible for updating data

**Contact****Name of organization / entity**

Department of oral diseases, Dental School of Babol University of Medical Sciences

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Neda Babaee

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Assistant professor, DDS, MS

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Department of oral diseases, Dental School of Babol University of Medical Sciences, Felestin Str, Velayat square

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Babol

**Postal code****Phone**

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**Fax****Email**

n.babaee@mubabol.ac.ir;  
dr\_nedababaee@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*