

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### A comparison study of the therapeutic effect of " topical steroid" and "honey plus coffee" on Oral Mucositis after chemotherapy and/or radiotherapy.

#### Protocol summary

##### Summary

The aim of this randomized, double blind study is to evaluate and compare the therapeutic effects of topical steroid with honey plus coffee in the treatment of patients with Oral Mucositis after chemotherapy and/or radiotherapy. A total of about 75 adult participants who are experiencing Oral Mucositis after chemotherapy and/or radiotherapy, are assigned into the following three groups. For all the participants a syrup-like solution is prepared. Each 500 cc of the product consisted of "20 ampoules that each one contained 8 mg Betamethasone" in the first group, "300 grams of honey plus 20 grams of instant coffee" in the second group, and placebo for the third group. These participants are told to sip 10 cc of the prescribed product, and then swallow it every 3 hours for one week. Severity of lesions is evaluated before and after the treatment and also one week after the intervention and is compared between three groups. This study is in the 3rd phase now.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201104074737N3**

Registration date: **2011-05-09, 1390/02/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-05-09, 1390/02/19

##### Registrant information

###### Name

Mohammad Ali Raeessi

###### Name of organization / entity

Baqiyatallah University of Medical Sciences and Health Services

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8803 0514

##### Email address

raeessi@bmsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Dr. Mohammad Ali Raeessi + Baqiyatallah University of Medical Sciences

##### Expected recruitment start date

2009-03-21, 1388/01/01

##### Expected recruitment end date

2011-09-21, 1390/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparison study of the therapeutic effect of " topical steroid" and "honey plus coffee" on Oral Mucositis after chemotherapy and/or radiotherapy.

##### Public title

A comparison study of the therapeutic effect of " topical steroid" and "honey plus coffee" on Oral Mucositis after chemotherapy and/or radiotherapy.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Oral Mucositis after chemotherapy and/or radiotherapy /age between 15 and 80 years.

Exclusion criteria: Out of this age range - presence of other systemic disease and gastrointestinal disorders.

### Age

From **15 years** old to **80 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **75**

### 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

Ethic Committee in Medical Sciences Research,  
Deputy of Research and Technology, Baqiyatallah  
Univer

##### Street address

Sheikhbahaee St., Mollasadra Ave

##### City

Tehran

##### Postal code

Postcode: 14359 - P.

#### Approval date

2009-03-16, 1387/12/26

#### Ethics committee reference number

C/340/10/15/100

## Health conditions studied

### 1

#### Description of health condition studied

K13.7 Other and unspecified lesions of oral mucosa

#### ICD-10 code

K13.7

#### ICD-10 code description

K13.7

## Primary outcomes

### 1

#### Description

Oral Mucositis after chemotherapy and/or radiotherapy.

#### Timepoint

Before and after the treatment and also one week after the treatment

#### Method of measurement

Oral lesions: normal (0), low (+), moderate (++), and severe (+++)

## Secondary outcomes

### 1

#### Description

Pain

#### Timepoint

Before and after the treatment and also one week after the treatment

#### Method of measurement

Normal (0), low (+), moderate (++), and severe (+++)

## Intervention groups

### 1

#### Description

Intervention1 : 500 ml solution containing 20 ampoules that each one contained 8 mg betamethasone" The participants are told to sip 10 cc of the prescribed product, and then swallow it every 3 hours for one week

#### Category

Treatment - Other

### 2

#### Description

Intervention2 : 500 ml solution containing 300gram honey and 20 gram coffee; The participants are told to sip 10 cc of the prescribed product, and then swallow it every 3 hours for one week

#### Category

Treatment - Drugs

### 3

#### Description

Intervention3: 500 ml solution containing placebo" The participants are told to sip 10 cc of the prescribed product, and then swallow it every 3 hours for one week

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Baqiyatallah University Hospital of Medical Sciences (and the Hospital)

**Full name of responsible person**

Dr. Mohammad Ali Raeessi

**Street address**

Sheikhbahaee St., Mollasadra Ave

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Dr. Mohammad Ali Raeessi + Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Ali Raeessi

**Street address**

No117, Molasadra residential complex, Kharazmi st., Mollasadra Ave.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Dr. Mohammad Ali Raeessi + Baqiyatallah 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**

Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Ali Raeessi

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

No: 117, Mollasadra residential complex, Kharazmi St, Mollasadra Ave.

**City**

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**Postal code**

1435913118

**Phone**

+98 21 8803 0514

**Fax**

**Email**

raeessi\_ma@yahoo.com; raeessi@bmsu.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Baqiyatallah University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant professor

**Other areas of specialty/work**

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## Person responsible for updating data

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**Name of organization / entity**

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**Full name of responsible person**

Dr. Mohammad Ali Raeessi

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Assistant Prof.

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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*