Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 UniversityHospital 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 residental 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 residental complex, Kharazmi St, Mollasadra Ave.

City
Tehran

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
Dr. Mohammad Ali Raeessi

Position
Assistant professor

Other areas of specialty/work

Street address
No 117, Molasadra residental complex, Kharazmi st., Mollasadra Ave.

City
Tehran

Postal code
1435913118

Phone
+98 21 8803 0514

Fax

Email
raeessi_ma@yahoo.com; raeessi@bmsu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Baqiyatallah Universityof Medical Sciences

Full name of responsible person
Dr. Mohammad Ali Raeessi

Position
Assistant Prof.

Other areas of specialty/work

Street address
No: 117, Molasadra residental complex, Kharazmi St., Mollasadra Ave.

City
Tehran

Postal code
1435913118

Phone
+98 21 8803 0514

Fax

Email
raeessi_ma@yahoo.com; raeessi@bmsu.ac.ir

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