Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assesment of Satureja khuzestanica topical preparation chemotherapy-induced Mucositis

Protocol summary

Summary

Oral mucositis is a common complication of many cancer treatments that has an adverse impact on the quality of life of patient. It is characterized by painful erythematous and ulcerative lesions. Satureja Khuzestanica is an endemic plant of Iran. Satureja khuzestanica has anti-inflammatory, antifungal, antimicrobial, antiviral properties. The purpose of this study was to evaluate the local effect of satureja oral gel in prevention of oral mucositis. A randomized clinical trial was carried out in order to evaluate the effect of satureja oral gel for prevention of oral mucositis. 50 diagnosed cancer patients were recruited. All patients were on main chemotherapeutic agents which are associated with oral mucositis as a main side effect. Patients were divided into two groups of 25. Group A are patients who are going under chemotherapy treatment with general oral care, group B are patients with similar regimen but supplied with satureja oral gel. Patients were assessed at baseline and at the end of each cycle using visual examination as well as using the Patient-Reported Oral Mucositis Symptom (PROMS) scale and Oral Mucositis Assessment Scale (OMAS) questionnaires. Patients were followed for a period of three cycles.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412153106N20**
Registration date: **2014-12-30, 1393/10/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-12-30, 1393/10/09

Registrant information

Name

Farshad Hashemian

Name of organization / entity

Pharmaceutical Sciences Branch, Islamic Azad University (IAU)

Country

Iran (Islamic Republic of)

Phone

+98 21 2260 0037

Email address

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Recruitment status

Recruitment complete

Funding source

Pharmacutical Sciences Branch of Islamic Azad University

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assesment of Satureja khuzestanica topical preparation chemotherapy-induced Mucositis

Public title

Assesment of Satureja khuzestanica topical preparation chemotherapy-induced Mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: consciousness; being literate; chemotherapeutic management with drugs which induce mucositis; no stomatitis; no oral disease; no renal & liver

disorders; no auto immune disease and diabetes; no fever and neutropenia; no recieved antibiotic & narcotic analgesic.

Age
From **20 years** old to **77 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Pharmaceutical Sciences Branch of Islamic Azad University

Street address
No99,Yakhchal street, Shariati street

City
Tehran

Postal code
1941933111

Approval date
2013-08-27, 1392/06/05

Ethics committee reference number
4858

Health conditions studied

1

Description of health condition studied
Mucositis

ICD-10 code
K13

ICD-10 code description
Other diseases of lip and oral mucosa

Primary outcomes

1

Description
Mucositis

Timepoint
At the end of cycle for 3 cycles

Method of measurement
PROMS and OMAS questionnaires

Secondary outcomes

1

Description
Mucositis

Timepoint
At the end of cycle for 3 cycles

Method of measurement
PROMS and OMAS questionnaires

Intervention groups

1

Description
Intervention group: general oral care with Satureja Khuzestanica oral gel, from the first day up the end of cycle for 3 cycles.

Category
Treatment - Drugs

2

Description
Control group: standard drug therapy recommended by the physician

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Boali hospital

Full name of responsible person
Dr. Abdolali Shahrasbi

Street address
Bouali hospital, Damavand avenue, Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pharmaceutical Science branch of Islamic Azad University

Full name of responsible person

Dr. Sepideh Arbabi Bidgoli

Street address

No.99, Yakhchal street, Dr. Shariati Avenue Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pharmaceutical Science branch of Islamic Azad University

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Pharmaceutical Sciences branch of Islamic Azad University

Full name of responsible person

Dr. Mehdi Rajabi

Position

Assistant professor / Head of Department

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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