Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Glutamine Oral gel onprevention of 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. When Glutamine is administered via oral drug delivery, it can reduce oral mucositis, however, not significant as it has low solubility and absorption. The purpose of this study was to evaluate the local effect of glutamine oral gel in prevention of oral mucositis. A randomized clinical trial was carried out in order to evaluate the effect of glutamine 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 glutamine 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: **IRCT201411153106N19**
Registration date: **2014-12-12, 1393/09/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-12-12, 1393/09/21

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

hashemian.f@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

Islamic Azad University, pharmaceutical sciences branch

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Glutamine Oral gel onprevention of chemotherapy-induced mucositis

Public title

The effect of Glutamine Oral gel onprevention of 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 Exclusion criterion: sensitivity to glutamine oral gel.

Age
From **20 years** old to **75 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
IAUPS branch of pharmaceutical sciences

Street address
pharmacutical sciences branch,Islamic AZAD university,Yakhchal street,Shariati street

City
Tehran

Postal code
1941933111

Approval date
2013-12-31, 1392/10/10

Ethics committee reference number
4857

Health conditions studied

1

Description of health condition studied
Oral mucositis

ICD-10 code
K12.3

ICD-10 code description
Oral mucositis (ulcerative)

Primary outcomes

1

Description
Mucositis

Timepoint
At the end of cycle for 3 cycles

Method of measurement
PROMS and OMAS questionnaires

Secondary outcomes

empty

Intervention groups

1

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

Category
Treatment - Drugs

2

Description
Control group: general oral care

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani hospital

Full name of responsible person
Dr. Abdolali Shahrasbi

Street address

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 science branch of Islamic Azad university
Full name of responsible person
Dr. Mehdi Rajabi
Position
Assistant professor / Head of Department
Other areas of specialty/work
Street address
No.99, Yakhchal street, Dr. Shariati Avenue
City
Tehran
Postal code
Phone
+98 21 2246 0056
Fax
Email
mehdirj@aol.co.uk
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