

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

The effect of Glutamine Oral gel on prevention 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)

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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 on prevention of chemotherapy-induced mucositis

Public title

The effect of Glutamine Oral gel on prevention 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 received 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

pharmaceutical 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

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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