

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of L-carnitine effect on prevention of chemotherapy-induced oral mucositis , A prospective, randomized, double-blind, controlled trial

Protocol summary

Summary

Whereas chemotherapy-induced oral mucositis is a painful and uncomfortable side effect and affects the quality of life and the patient's tolerance for continued treatment, it is important to treat this problem. This study was performed aimed to investigate the effect of L-Carnitine in the treatment of oral mucositis caused by chemotherapy. This study is double-blind randomized clinical trial and will take place on 40 patients over 18 years old and under chemotherapy referring to Imam Khomeini hospital. Blinding was conducted for groups of subjects (patients) participants to measure the outcomes of study (researchers) and data monitoring committee (Recent analysis). Inclusion criteria of the study: bedridden in Oncology unit, consent to participate in the study, without using drugs or any vitamin and mineral carnitine in the past 8 weeks, over 18 years old, Exclusion criteria: the risk of side effects such as nausea or any time the patient refuse to participate in the study. Patients before inclusion are examined of oral health and risk factors of developing oral mucositis. Patients who have inclusion criteria, based on randomized block design in two groups of 20 patients who received the drug or placebo are placed. Patients' demographic information such as age, sex, weight, diagnosis, date of hospitalization, tests, history of other diseases and medication instructions will be registered. In the first group of L-Carnitine at a dose of 3 grams per day and the second group received placebo daily for three weeks since the start of chemotherapy. Of all patients at baseline, before administration of L-Carnitine and then at intervals of one week 10 ml blood samples for biochemical evaluation and testing of the CBC is taken. The use of L-Carnitine and patient adherence to medication side effects, the incidence of mucositis grade rating according to WHO, will be checked every week . During treatment the patient received amount of L-Carnitine also be controlled.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102265914N1**

Registration date: **2017-10-02, 1396/07/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-02, 1396/07/10

Registrant information

Name

Shima Hatamkhani

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Science Faculty of Pharmacy

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of L-carnitine effect on prevention of chemotherapy-induced oral mucositis , A prospective, randomized, double-blind, controlled trial

Public title

Evaluation of L-carnitine effect on prevention of chemotherapy-induced oral mucositis , A prospective, randomized, double-blind, controlled trial

Purpose

Prevention

Inclusion/Exclusion criteria

Exclusion criteria: the risk of side effects such as nausea or whenever the patient refuse to participate in the study
Inclusion criteria of the study: bedridden in Oncology unit, consent to participate in the study, without using drugs or any vitamin and mineral carnitine in the past 8 weeks, aged over 18 years

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Ethics Committee of Urmia University of Medical Sciences

Street address

Emergency alley, Resalat street

City

Urmia

Postal code

Approval date

2016-11-09, 1395/08/19

Ethics committee reference number

ir.umsu.rec.1395.335

Health conditions studied

1

Description of health condition studied

mucositis

ICD-10 code

k12.3

ICD-10 code description

Oral mucositis (ulcerative)

Primary outcomes

1

Description

oral mucositis

Timepoint

weekly

Method of measurement

observation

2

Description

CBC

Timepoint

weekly

Method of measurement

blood sample

Secondary outcomes

empty

Intervention groups

1

Description

l-carnitine 1gr tablets 3 times a day for 3 weeks

Category

Treatment - Drugs

2

Description

placebo 1gr tablets 3 times a day for 3 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Urmia

Full name of responsible person

Street address

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Urmia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

Street address

Emergency alley, Resalat street

City

Urmia

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Urmia 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

Faculty of Pharmacy of Urmia

Full name of responsible person

Shima Hatamkhani

Position

Clinical Pharmacist / Assistant professor

Other areas of specialty/work

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Position

Pharm D / student

Other areas of specialty/work

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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