Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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 Hatamkhnai
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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