Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Low level laser effect in preventing the incidence of chemotherapy-induced oral mucositis in patients with acute leukemia

Protocol summary

Summary

Purpose: low level laser effect in preventing the incidence of chemotherapy-induced oral mucositis in patients with acute leukemia. The study design: randomized, double-blinded. The study population: myeloid/lymphoblastic acute leukemia receiving myeloablative chemotherapy regimen. Inclusion criteria:12-70 y/o, healthy oral mucosa at the beginning of the study, receiving myeloablative chemotherapy regimen. Exclusion criteria: unhealthy oral mucosa (erythema, ulcer, soreness) at the beginning of the study, non ablative chemotherapy regimen. Sample size: 40. Intervention: low level laser (He-Ne). Primary outcome: reducing the incidence of ulcer and erythema.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110157801N1**
Registration date: **2011-10-23, 1390/08/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-10-23, 1390/08/01

Registrant information

Name

Sara Mogharrabi

Name of organization / entity

Dental school, Shiraz university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Dental faculty, Shiraz university of medical sciences

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2012-04-20, 1391/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Low level laser effect in preventing the incidence of chemotherapy-induced oral mucositis in patients with acute leukemia

Public title

Laser effect in preventing the incidence of chemotherapy-induced oral ulcers in patients with acute leukemia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 12-70 y/o; both genders; suffering acute myeloid/lymphoblastic leukemia; receiving myeloablative chemotherapy regimen; healthy oral mucosa at before starting chemotherapy; able to cooperation; filling the informed consent form. Exclusion criteria: unhealthy oral mucosa (erythema, ulcer, soreness) before starting chemotherapy; non ablative chemotherapy regimen; inability or unwillingness for being involved.

Age

From **12 years** old to **70 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
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz university of medical sciences
Street address
Central building of shiraz university of medical sciences, Namazi square
City
Shiraz
Postal code
Approval date
2011-01-21, 1389/11/01
Ethics committee reference number
CT- 86-38-79

Health conditions studied

1

Description of health condition studied
acute lymphoblastic leukemia
ICD-10 code
C91.0
ICD-10 code description
Acute lymphoblastic leukaemia

2

Description of health condition studied
acute myeloid leukemia
ICD-10 code
C92.0
ICD-10 code description
Acute myelblastic leukaemia

Primary outcomes

1

Description
reducing the incidence of ulcer and erythema
Timepoint
1 week, 2 weeks, 3 weeks, 4 weeks
Method of measurement
observation of the erythema and ulcer accordig to WHO & NCI scale

Secondary outcomes

1

Description
reducing pain
Timepoint
1 week, 2 weeks, 3 weeks, 4 weeks
Method of measurement
explaining the amount of pain according to the patients' expression (1-10 numbers)

Intervention groups

1

Description
For all participants in both groups, a prophylactic phase will be started from the first day of chemotherapy. In this phase standard oral hygiene will be recommended, furthermore chlorhexidine 0.12%, 3 time a day and nystatin oral drop 3 time a day will be prescribed from the first day of hospitalization till the last day (for about 4 weeks).
Category
Prevention

2

Description
In intervation group, low level laser (660nm, 25 mw and 1.5 J/cm2) will be applied on 18 different points in the mouth, 2 times a week during chemotherapy.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Bone marrow transplantation department, Namazi hospital
Full name of responsible person
Dr. Mani Ramzi
Street address
Namazi hospital
City

Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Dental faculty, Shiraz university of medical sciences
Full name of responsible person
Dr. Mohammad Mehdi Fani
Street address
Shiraz dental faculty, Ghasre-Dasht street
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Dental faculty, Shiraz 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
Oral medicine department, Dental faculty
Full name of responsible person
Dr.Mohammad Mehdi Fani
Position
Associate Professor
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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