Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Affect of Achillea millefolium in Prophylaxis of oral mucositis induced by chemotherapy in AML patients.

Protocol summary

Summary

Aim of this research is to study prophylactic effect of Achillea millefolium extract on oral mucositis in AML patients. This randomized study is performed in Shahid Ghazi hospital in Tabriz. Cases are chosen from AML male or female patients aged 16 to 85 who are candidate for chemotherapy. Pregnant patients and those who are not volunteer or have less than 3 weeks of hospitalization and patients with existence mucositis will be excluded. 18 patients will be chosen randomly and they will be divided to two groups by random allocation. Intervention group will received 10 to 15 ml of Achillea mouthwash twice daily in addition towards normal treatments(chlorhexidine mouthwash). The other group will receive routine regimen(control group). Clinical signs and quality of life of patients will be recorded a form. CBC will be measured. Patients' oral mucositis will be graded by WHO mucositis scale. Amount of analgesics consumed, duration and severity of mucositis will be register on day1 until day 21 of chemotherapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201309215704N2**
Registration date: **2014-04-12, 1393/01/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-04-12, 1393/01/23

Registrant information

Name

Simin Ozar Mashayekhi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Hematology and Oncology Research Center, Tabriz University of Medical Sciences, Iran

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2014-06-05, 1393/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Affect of Achillea millefolium in Prophylaxis of oral mucositis induced by chemotherapy in AML patients.

Public title

Affect of Achillea millefolium in Prophylaxis of oral mucositis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: AML patients including both male or female ones, aged between 16-85 who are candidate for chemotherapy; Exclusion criteria: Pregnancy; Patients who are not volunteer; Patients with less than 3 weeks duration of hospitalization; Patients with mucositis

Age

From **16 years** old to **85 years** old

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **18**
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
Ethics Committee of Tabriz University of medical Sciences
Street address
Daneshgah St, 2nd main Building, Vice Chancellor for research, Tabriz University of Medical Science
City
Tabriz
Postal code
51664-14766
Approval date
2013-12-02, 1392/09/11
Ethics committee reference number
92144

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
Duration of mucositis
Timepoint
From begining of chemotherapy until 21 days later
Method of measurement
Counting number of days

2

Description
Severity of mucositis
Timepoint
First day of chemotherapy until 21 days later
Method of measurement
WHO oral mucositis scale

Secondary outcomes

1

Description
Amount of analgesics requested for pain caused by mouth sores
Timepoint
First day of chemotherapy until 21 days later
Method of measurement
Type and dosage of analgesics recorded in patients records in 21 days duration

Intervention groups

1

Description
Intervention group will receive hospital's routine prophylactic therapy, which is cholorhexidine mouthwash, and Achillea's extract mouthwash. After preparation of Achillea's extraction, it is used for preparation of mouthwash formulation, which will be used 10 to 15 ml twice daily. Achillea and cholorhexidine mouthwash will be used in different times of day. Patients will be asked not to eat, drink or wash their mouth for 1.5 hours after using mouthwash. During 21 days, presence of mucositis, its duration, severity and type and dose of used analgesics will be recorded.
Category
Treatment - Drugs

2

Description
Control group will receive hospital's routine prophylactic therapy, which is cholorhexidine mouthwash. 5 ml Cholorhexidine mouthwash will be used once daily. Patients will be asked not to eat, drink or wash their mouth for 1.5 hours after using mouthwash. During 21 days, presence of mucositis, its duration, severity and type and dose of used analgesics will be recorded.
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Ghazi hospital Tabriz

Full name of responsible person
Dr Simin Mashayekhi,PhD, Assistant professor

Street address
Faculty of Pharmacy, Daneshgah St,

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hematology and Oncology Research Center, Tabriz University of Medical Sciences, Iran

Full name of responsible person
Mohammadreza Rashidi

Street address
Vice Chancellor for research,Tabriz University of Medical Science, 2nd main Building, Daneshgah St.

City
Tabriz

Grant name

Grant code / Reference number

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

Title of funding source
Hematology and Oncology Research Center, Tabriz University of Medical Sciences, Iran

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
Tabriz University of Medical Sciences

Full name of responsible person
Simin Mashayekhi

Position
PhD, Assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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