

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 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)

Phone

+98 41 1337 2250

Email address

mashayekhis@tbzmed.ac.ir

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 beginning 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 chlorhexidine 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 chlorhexidine 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 chlorhexidine mouthwash. 5 ml Chlorhexidine 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**Street address**

Faculty of Pharmacy, Daneshgah St

City

Tabriz

Postal code**Phone**

+98 41 1339 2593

Fax**Email**

mashayekhis@tbzmed.ac.ir

Web page address

Person responsible for scientific 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**Street address**

Faculty of Pharmacy, Daneshgah St

City

Tabriz

Postal code**Phone**

+98 41 1339 2593

Fax**Email**

mashayekhis@tbzmed.ac.ir

Web page address

Person responsible for updating data

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**Street address**

Faculty of Pharmacy, Daneshgah St

City

Tabriz

Postal code**Phone**

+98 41 1339 2593

Fax**Email**

mashayekhis@tbzmed.ac.ir

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