

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

A comparative study on the effect of mouthwash of licorice root extract with combination mouthwash on the incidence and severity of mucositis symptoms Caused by chemotherapy in colon cancer patients Admitted in the ICU

Protocol summary

Study aim

The application of anti-inflammatory effects of Licorice in the improvement of chemotherapy-induced mucositis symptoms

Design

Clinical trial with control and intervention group based on purpose, with parallel groups, blind and randomized trials

Settings and conduct

The study was available on a targeted basis and blinded by all patients with cancer in the ICU

Participants/Inclusion and exclusion criteria

Under periodic chemotherapy. Mucositis . People under colon cancer chemotherapy (:) Along with chemotherapy, they will also be radiotherapy Transfer to another health facility

Intervention groups

Based on the criteria for entry, the patients were selected and randomly divided into control and intervention groups.

Main outcome variables

Mucositis Severity of mucositis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180109038281N1**

Registration date: **2018-04-12, 1397/01/23**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-12, 1397/01/23**

Update count: **0**

Registration date

2018-04-12, 1397/01/23

Registrant information

Name

amin sattari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3320 0627

Email address

criticalcare95@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-11, 1396/12/20

Expected recruitment end date

2018-06-10, 1397/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of mouthwash of licorice root extract with combination mouthwash on the incidence and severity of mucositis symptoms Caused by chemotherapy in colon cancer patients Admitted in the ICU

Public title

The effect of licorice in mucositis caused by chemotherapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Aged 18 years and older Under periodic chemotherapy. Mucositis patients undergoing full-fox cancer chemotherapy, which include (,Oxalipatin - Leucovorin , 5-fluorouracil) for at least one week in the hospital. Not having asthma and other allergic diseases

Exclusion criteria:
Radiation therapy is also associated with chemotherapy. Transfer to another health center. Death during treatment.

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized block random block method with block size 6 (using a random permutation table).

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this research, according to a randomized list, is assigned by a person outside the study according to the corresponding codes in the sealed envelopes, then assigned to any disease that is included in the study. Medications are identical in appearance, packaging, color, and so on. The nature of the drugs is revealed after the analysis of the results.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Building of Honey Plate 288, Street Tir-Dee and Bahman Blvd. Golestan

City

Ahvaz

Province

Khouzestan

Postal code

69816-41154

Approval date

2018-02-03, 1396/11/14

Ethics committee reference number

IR.AJUMS.REC.1396.942

Health conditions studied

1

Description of health condition studied

Mucositis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mucositis

Timepoint

At the beginning of the intervention, 3 and 7 days after the start of oral mucosal administration

Method of measurement

Oral Mucositis Assessment Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients receiving oral liquorice mouthwash at a concentration of 5%, 10 cc for one week and three times a day, are used as water soluble.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghaee Hospital 2- Intensive Care Unit

Full name of responsible person

Abdul Ali Shariati

Street address

Baghaee Hospital 2- Golestan Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
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Grant name

Deputy of Research and Technology Development of
Jundishapur University of Medical Sciences, Ahvaz

Grant code / Reference number

IR.AJUMS.REC.1396.942

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

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
aminsattari
Position
student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available