Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 pationts 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

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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

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Baghaee Hospital 2- Golestan Blvd.

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Person responsible for updating data

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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