

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### clinical effectiveness of mouthwash of arctium lappa tincture on the treatment of oral mucositis induced by chemoradiotherapy in patients with head and neck cancer

#### Protocol summary

##### Study aim

Determination of the efficacy of mouthwash from infusion of tincture of burdock on mucositis treatment following comorbidothrapy in patients with head and neck cancer

##### Design

A parallel single blinded randomized clinical trial study  
sample size:52 patients

##### Settings and conduct

this study is a single blind clinical trial on patients with head and neck cancer who are referred to Rasht Razi hospital.52 patients will attended this study who will be randomly divided into two groups of cases and controls.patients should have grade 3 or 4 mucositis.severiety of mucositis and pain access and record at the begining of the study.patients in case groups are given burdock and Diphenhydramine mouthwash,patients in control groups are given Diphenhydramine mouthwash.the patients take medication for 6 weeks.the severity of the mucositis and pain are accessed once at the begining of the study,after the intervention,and then every week.the information obtained is based on the patient's questionnaire is recorded.allat the begining of the study,form of the agreement will be completed.

##### Participants/Inclusion and exclusion criteria

All patients with head and neck cancer can be included in the study regardless of age and sex. Patients with a history of specific systemic disease or a history of allergy to medicinal plants can not be included in the study.

##### Intervention groups

In the experimental group, mucosal tincture of burdock and Diphenhydramine mouthwash was used separately.

##### Main outcome variables

Evaluation of pain and severity of lesion changes and duration of treatment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190114042353N1**

Registration date: **2019-03-16, 1397/12/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-03-16, 1397/12/25**

Update count: **0**

##### Registration date

2019-03-16, 1397/12/25

##### Registrant information

##### Name

Masood Sepehrimanesh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3352 5259

##### Email address

sepehrimaneshmasood@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-20, 1397/12/01

##### Expected recruitment end date

2019-10-23, 1398/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

clinical effectiveness of mouthwash of arctium lappa tincture on the treatment of oral mucositis induced by chemoradiotherapy in patients with head and neck cancer

**Public title**

clinical effectiveness of mouthwash of arctium lappa tincture on the treatment of oral mucositis induced by chemoradiotherapy in patients with head and neck cancer

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All patients with head and neck cancer who go to oncology department of "Razi Hospital"

**Exclusion criteria:**

Patients with any systemic disorder that may interfere with the repair process (such as diabetes) History of allergy to Arauca family Pregnant and lactating women Continuous users of analgesics

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: 52

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization using a random number table

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

after accepting participation In the study, a bottle containing a mixture of burdock mouthwash and a diphenhydramine mouthwash was given to the patient that the patient was not aware of its contents.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of research center of Guilan University of Medical sciences

**Street address**

Guilan University of Medical Sciences.,Lakan Road

**City**

Rasht

**Province**

Guilan

**Postal code**

4194173774

**Approval date**

2019-01-19, 1397/10/29

**Ethics committee reference number**

IR.GUMS.REC.1397.411

**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**

The amount of pain

**Timepoint**

at the first of study before intervention, then it is measured every week for 6 weeks

**Method of measurement**

Based on the VAS index

**2****Description**

Severity of lesion

**Timepoint**

at the first of study before intervention, then it is measured every week for 6 weeks

**Method of measurement**

Based on the WHO Scale

**3****Description**

treatment duration

**Timepoint**

Total days from the onset of 3-4 degree mucositis symptoms

**Method of measurement**

Number of days

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: Mouthwash burdock Tincture + Diphenhydramine mouthwash: The patient should hold 30 drops of mouthwash with some water in his mouth every day, four times a day, and then throw it out. (Before using this mouthwash, they should also use diphenhydramine combination mouthwash). As they should, first, keep 30 drops of mouthwash for 30 seconds and then throw it away. After 30 minutes, use the second mouthwash in the manner described.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Diphenhydramine combination mouthwash: The patient takes 30 drops of diphenhydramine mouthwash four times a day for 30 seconds in his mouth then throw it away.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi Hospital In Rasht

##### Full name of responsible person

masood sepehrimanesh

##### Street address

Radiotherapy Department Of Razi Hospital, Sardar Jangal Ave, Rasht

##### City

Rasht

##### Province

Guilan

##### Postal code

41448

##### Phone

+98 13 3353 5116

##### Email

sepehrimaneshmasood@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-Chancellor of Research Affairs, Guilan University of Medical Sciences

##### Full name of responsible person

Shadman Nemati

##### Street address

Guilan University of Medical Sciences, 2km Fouman

Road, Lakan Road

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##### Province

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##### Postal code

4194173774

##### Phone

+98 13 3332 4168

##### Fax

+98 13 3332 4168

##### Email

sepehrimaneshmasood@gmail.com

##### Web page address

<http://www.gums.ac.ir/research>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Vice-Chancellor of Research Affairs, Guilan 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

Rasht University of Medical Sciences

##### Full name of responsible person

Anahid Lavayii Motlagh

##### Position

dental student

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dentistry

##### Street address

Guilan University of Medical Sciences, 2km Fouman Road, Lakan Road

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##### Email

dr.anahid@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

masood sepehri manesh

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Clinical Research

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Rasht University of Medical Sciences

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Anahid Lavayii Motlagh

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dental student

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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**

Care for the secrets of patients

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available