

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

City

Rasht

Province

Guilan

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

City

Rasht

Province

Guilan

Postal code

4194173774

Phone

+98 13 3348 6406

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

Street address

Research Center Lab,Razi Hospital,Sardar Jangal Ave,Rasht

City

Rasht

Province

Guilan

Postal code

41448

Phone

+98 13 3353 5116

Email

sepehrimaneshmasood@gmail.com

Person responsible for updating data

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

City

Rasht

Province

Guilan

Postal code

4194173774

Phone

+98 13 3348 6406

Email

dr.anahid@yahoo.com

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