

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of the effects of curcumin capsules on prevention and prognosis of chemotherapy and radiotherapy induced oral mucositis in patients with cancer

Protocol summary

Study aim

Evaluation of the effects of curcumin capsules on prevention and prognosis of chemotherapy and radiotherapy induced oral mucositis

Design

In this two arm parallel group randomized clinical trial with blinded postoperative care and outcome assessment, we divide the patients who refer to Rasht Razi hospital for any organ cancer chemotherapy and head and neck radiotherapy into two 25-patients group. The study group takes 80 mg Curcumin capsule twice a day and the control group takes placebo twice a day for 7 weeks since the onset of their treatment. The presence and severity of erythema and erosion will be measured by WHO criteria and the amount of pain will be recorded by NRS at the onset of study, end of the first, second, fourth and seventh weeks. Afterward, data will be analyzed by SPSS 22 software.

Settings and conduct

We put Curcumin capsules and placebo in apparently similar bottles and neither the researcher nor the patients knows the contents of them. The presence and severity of erythema and erosion will be measured by WHO criteria and the amount of pain will be recorded by NRS at the onset of study, end of the first, second, fourth and seventh weeks. Afterward, data will be analyzed by SPSS 22 software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients under head and neck radiotherapy patients under chemotherapy Exclusion criteria: patients with oral lesions patients with systemic diseases smoking

Intervention groups

Study group: patients take 80 mg Curcumin capsules twice a day during 7 weeks since the onset of chemotherapy and radiotherapy. Control group: patients take placebo twice a day during 7 weeks since the onset

of chemotherapy and radiotherapy.

Main outcome variables

Mucositis induced by chemotherapy and radiotherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100101002950N6**

Registration date: **2019-02-12, 1397/11/23**

Registration timing: **prospective**

Last update: **2019-02-12, 1397/11/23**

Update count: **0**

Registration date

2019-02-12, 1397/11/23

Registrant information

Name

Sayed Javad Kia

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1323 0775

Email address

djavadkia@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2019-05-05, 1398/02/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effects of curcumin capsules on prevention and prognosis of chemotherapy and radiotherapy induced oral mucositis in patients with cancer

Public title
Evaluation of the effects of curcumin capsules on prevention and prognosis of chemotherapy and radiotherapy induced oral mucositis in patients with cancer

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients under head and neck radiotherapy Patients under chemotherapy
Exclusion criteria:
Patients with oral lesions Patients with systemic diseases Smoking

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: 50

Randomization (investigator's opinion)
Randomized

Randomization description
We divide people into two random groups containing 25 number of patients by giving them numbers from 1 to 50. Afterward we divide patients into two different group by SAS 9.1 software randomly.

Blinding (investigator's opinion)
Double blinded

Blinding description
We put Curcumin capsules and placebo in apparently similar bottles and neither the researcher nor the patients knows the contents of them.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of guilan university of medical science

Street address

opposite of sepah bank, western shahid beheshti blv

City

Rasht

Province

Guilan

Postal code

41941-73774

Approval date

2018-11-02, 1397/08/11

Ethics committee reference number

IR.Gums.Rec.1397.296

Health conditions studied

1

Description of health condition studied

Oral mucositis induced by chemotherapy and radiotherapy

ICD-10 code

K12.31

ICD-10 code description

Oral mucositis (ulcerative) due to antineoplastic therapy

Primary outcomes

1

Description

Oral mucositis

Timepoint

onset of treatment, first week, second week, fourth week and seventh week

Method of measurement

Severity of erythema and ulceration by WHO and amount of pain by NRS

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will take 80 mg Curcumin capsule produced by Exir Nano Sina company twice a day during 7 weeks since the onset of chemotherapy and radiotherapy

Category

Prevention

2

Description

Control group: This group will take placebo capsule produced by Sobhandaru Rash company twice a day during 7 weeks since the onset of chemotherapy and radiotherapy

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasht Razi Hospital

Full name of responsible person

Dr Seyed Javad Kia

Street address

Razi hospital, Sradarjungal St,

City

Rasht

Province

Guilan

Postal code

41448

Phone

+98 13 3354 1001

Email

razi.hospital@yahoo.com

Web page address

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

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr Shadman Nemati

Street address

In front of the 17 Shahrivar hospital, Siadati St, Namju St

City

Rasht

Province

Guilan

Postal code

41941-73774

Phone

+98 13 3333 6394

Fax

+98 13 3333 6395

Email

research@gums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Dr Seyed Javad Kia

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Fouman - Saravan Rd, Guilan university of medical sciences complex

City

Rasht

Province

Guilan

Postal code

41941-73774

Phone

+98 13 3348 6406

Fax

+98 13 3348 6423

Email

Djavadkia@gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr Seyed Javad Kia

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Fouman - Saravan Rd, Guilan university of medical sciences complex

City

Rasht
Province
Guilan
Postal code
41941-73774
Phone
+98 13 3348 6406
Fax
+98 13 3348 6423
Email
Djavadkia@gums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr Seyed Javad Kia
Position
Assitant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Fouman - Saravan Rd, Guilan university of medical sciences complex
City
Rasht
Province
Guilan
Postal code
41941-73774
Phone
+98 13 3348 6406
Fax

+98 13 3348 6423
Email
Djavadkia@gums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data are shareable after making them unidentifiable

When the data will become available and for how long

accessibility starts from 6 month after being published

To whom data/document is available

data will be accessible for researchers of universal and scientific institution

Under which criteria data/document could be used

They can use them if they state reference

From where data/document is obtainable

Dr Seyed Javad Kia djavadkia@yahoo.com

What processes are involved for a request to access data/document

after receiving the request, data will be send to applier during 1 month

Comments