Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 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 smokiing

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, Sradarjangal 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