Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the efficacy of nanomisel curcumin in preventing and treating oral candidiasis of patients undergoing head and neck radiation therapy

Protocol summary

Study aim
Determination of the effect of nanomisel curcumin in preventing and treating oral candidiasis of patients undergoing head and neck radiation therapy

Design
A randomized, double blinded, clinical trial(phase III) for 40 patients has been designed. Randomization is performed using a computer-generated random number table.

Settings and conduct
This double-blind randomized clinical trial is conducted at Mashhad Dental School, Iran. Participants and care providers and assessing outcomes and the statistician are blinded to the type of drug because drugs are placed in similar seal envelope packs.

Participants/Inclusion and exclusion criteria
Inclusion criteria: the minimum age of 18 years, presence of head and neck cancer, radiation dose of 50-70 Gy, at least 50% of patient's oral cavity in the field of radiation and patient satisfaction. Exclusion criteria included: previous history of radiation therapy, patient dissatisfaction, history of allergy to turmeric, , in case of any oral lesions or complication resulting from radiation therapy other than candidiasis and mucositis, use of systemic or topical antifungal drugs for any reason, pregnancy or breastfeeding periods in women under treatment, presence of local and systemic conditions predisposing for candidiasis, such as the application of inhaled and topical steroids, presence of hyperkeratosis, use of immunosuppressive drugs, history of systemic antibiotic usage over the previous 2 weeks, the presence of CFU above 400/ml in the first culture or clinical evidence based on the presence of oral candidiasis.

Intervention groups
The study group: nanocurcumin soft gel (containing 80 mg curcumin) are administrated orally once daily. The control group: placebo tablets areadministrated orally once daily.

Main outcome variables
Frequency of oral candidiasis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180416039318N3**
Registration date: **2018-06-02, 1397/03/12**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-02, 1397/03/12**
Update count: **0**

Registration date
2018-06-02, 1397/03/12

Registrant information

Name
Ala Ghazi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3882 9501

Email address
ghazial@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-07-23, 1397/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the efficacy of nanomisel curcumin in preventing and treating oral candidiasis of patients undergoing head and neck radiation therapy

Public title
Assessing the effect of nanomisel curcumin on prevention and treatment of nanomisel curcumin
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
the minimum age of 18 years, presence of head and neck cancer, radiation dose of 50-70 Gy, at least 50% of patient's oral cavity in the field of radiation and patient satisfaction.
Exclusion criteria:
previous history of radiation therapy, patient dissatisfaction, history of allergy to turmeric, , in case of any oral lesions or complication resulting from radiation therapy other than candidiasis and mucositis, use of systemic or topical antifungal drugs for any reason, pregnancy or breastfeeding periods in women under treatment, presence of local and systemic conditions predisposing for candidiasis, such as the application of inhaled and topical steroids, presence of hyperkeratosis, use of immunosuppressive drugs, history of systemic antibiotic usage over the previous 2 weeks, the presence of CFU above 400/ml in the first culture or clinical evidence based on the presence of oral candidiasis.
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients are randomly divided into two groups, namely the Study and Control groups. Randomization is performed using a computer-generated random number table.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the prepared medicine packs are the same for the two groups. Packages are coded from 1 to 40 by an individual outside the study. Packages are randomly delivered to patients. The participants and care providers and assessing outcomes and statistician are blinded to type of drug.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Mashhad Dental School, Azadi Square, Vakilabad Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
911735984
Approval date
2015-09-09, 1394/06/18
Ethics committee reference number
IR.mums.sd.REC.1394.14

Health conditions studied

1

Description of health condition studied
Oral Candidiasis
ICD-10 code
B 37.0
ICD-10 code description
Candidal stomatitis/Oral thrush

Primary outcomes

1

Description
ccurrence of oral candidiasis
Timepoint
The first day of radiotherapy before radiation, every week until the end of the study
Method of measurement
Clinical examinations of oral lesion

2

Description
Candidate colony count in ml (colony forming unit = CFU)
Timepoint

before the study, in the third week and the final week of radiotherapy

Method of measurement

Cultivation of oral lesions

Secondary outcomes

1

Description

type of oral Candidiasis

Timepoint

before the study, in the third week and the final week of radiotherapy

Method of measurement

germ tube test and cultivation of oral lesions

Intervention groups

1

Description

Intervention group: nanocurcumin soft gel (containing 80 mg curcumin) are administrated orally once daily.

Category

Treatment - Drugs

2

Description

Control group: The control group: placebo tablets are administrated orally once daily.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

مرکز تخصصی رادیوتراپی و انکولوژی رضا

Full name of responsible person

Dr Zahra Delavarian

Street address

Misaq 19, Misaq Blvd, Vakil abad Blvd, Mashhad, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Mashhad University of Medical Sciences, Daneshgah St.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Sedigheh Modarres Mousavy

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Contact

Name of organization / entity
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Zahra Delavarian

Position
Professor

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Other areas of specialty/work
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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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Some data including demographic properties, signs and symptoms

When the data will become available and for how long
Two months after article publication.

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
It is permitted to use the data in other studies with reference.

From where data/document is obtainable
Dr.Sedigheh Modarres Mousavy, ModarresMS921@mums.ac.ir

What processes are involved for a request to access data/document
Sending email to authors. the authors will send data via email during 4 weeks

Comments