Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of the effect of topical vitamin K with placebo in the treatment of skin rash in patients with metastatic colon cancer treated with Cetuximab

Protocol summary

Study aim
Comparative study of the effect of topical vitamin K with placebo in the treatment of skin rash in patients with metastatic colon cancer treated with cetuximab

Design
A randomized, double-blinded, sham controlled clinical trial with parallel groups, phase 3, on 48 patients.

Settings and conduct
In this randomized double-blind clinical trial study, 48 patients with metastatic colorectal cancer who are candidates for receiving Cetuximab referred to Omid Hospital in Isfahan will be randomly divided into two groups. One group will receive vitamin K cream and the other group will receive a placebo. Then the grade of skin lesions will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion : Metastatic colorectal cancer patients treating with Cetuximab and skin rash Not inclusion : Receive any treatment containing vitamin K or any medication that interferes with topical vitamin K intake.

Intervention groups
Intervention group: Patients will use topical vitamin K 0.1% cream twice a day Control group: Patients will use topical creams, including cream base and without any other additives, twice a day.

Main outcome variables
Reduction of skin lesions' grade

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150304021338N3**
Registration date: **2021-09-20, 1400/06/29**
Registration timing: **registered_while_recruiting**
Last update: **2021-09-20, 1400/06/29**
Update count: **0**

Registration date
2021-09-20, 1400/06/29

Registrant information

Name
Mahnaz Roayaei

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 31 3776 7396

Email address
roayaei@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-16, 1400/06/25

Expected recruitment end date
2022-03-01, 1400/12/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the effect of topical vitamin K with placebo in the treatment of skin rash in patients with metastatic colon cancer treated with Cetuximab

Public title
The effect of topical vitamin K on skin rash

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with metastatic colorectal cancer that are candidates for treatment with Cetuximab . Patients with grade 1 to 4 skin lesions, after using Cetuximab(based on Common Terminology Criteria for Adverse Events4 (CTCAE4)) Be over 18 years old The patient should not undergo radiotherapy. Have a desire to participate in the study.

Exclusion criteria:

The patient has skin lesions before receiving cetuximab (including rash, acne, pustules, inflammatory erythema) Being pregnant or in breastfeeding duration Previous history of allergies to compounds containing vitamin K Has a psychiatric disorder that is not able to participate in the study For other reasons, he is taking drugs that have a drug interaction with topical vitamin K Be taking medicinal compounds containing vitamin K

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients wish to participate in the study will be randomly divided into two groups A and B, using Random allocation software. Patients will be randomly assigned to intervention or control groups by someone other than the main researcher and statistical analyst, so, the patient, main researcher and statistical analyst will not know that how patients are placed in each group (intervention or control).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, two drugs, topical Vitamin K cream and placebo, in terms of shape and color, are prepared in the same way and provided to the researcher. They also prescribe them without knowing the type of any of the drugs. Also, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Center of Medical Research - Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

81745319

Approval date

2021-07-16, 1400/04/25

Ethics committee reference number

IR.MUI.MED.REC.1400.326

Health conditions studied

1

Description of health condition studied

Skin rash

ICD-10 code

R21

ICD-10 code description

Rash and other nonspecific skin eruption

Primary outcomes

1

Description

Grade of skin lesions, based on Common Terminology Criteria for Adverse Events4 (CTCAE4)

Timepoint

At the beginning of the study and 4 and 8 weeks after using topical vitamin K.

Method of measurement

Based on CTCEA4

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with skin rash has been induced by Cetuximab,will use topical 0.1% vitamin K cream, including a combination of vitamin K1

(Phytonadione) produced by Caspian company and the cream base,twice a day for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients with skin rash has been induced by Cetuximab, will use topical cream, including cream base And without any other additives, twice a day for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Dr. Mahnaz Roayaei

Street address

Omid Hospital, Motahari Street, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3235 0210

Email

roayaei@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mahmoud Rezaei

Position

Radiation oncology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3235 0214

Fax

Email

dralirezarezaei1991@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahmoud Rezaei

Position

Radiation oncology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3235 0214
Fax
Email
dralirezarezaei1991@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mahmoud Rezaei
Position
Radiation oncology Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
Street address
Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3235 0214
Fax
Email
dralirezarezaei1991@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
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