

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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

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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

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Province

Isfahan

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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

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Omid Hospital, Motahari Street, Isfahan, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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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

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

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Position

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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