Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effect of formulated methylene blue basal cell carcinoma (BCC)

Protocol summary

Study aim
Determining the clinical effects of formulated methylene blue in reducing tumor size in basal cell carcinoma (BCC)

Design
Non-randomized phase 2-3 clinical trial on 20 patients

Settings and conduct
In this study, patients visit the skin clinic of Imam Reza Hospital and the treating physician selects and includes patients based on the inclusion and exclusion criteria. Methylene blue 0.5mg/ml solution and formulated ointment are applied topically to the lesion every two days for a month and the lesion is photographed. If the wound improves and shrinks, the same procedure is continued until complete healing, and if there is no improvement after one month, standard methylene blue photodynamic therapy is applied for another month. Also, if the patient agrees, tissue sampling will be used for pathological evaluation. Patients will be followed up for 6 months. The collected data will be analyzed with appropriate statistical methods and using SPSS software version 25

Participants/Inclusion and exclusion criteria
Informed and written consent of the patient to participate in the study. Diagnosis of basal cell carcinoma confirmed by pathology Patient unwillingness to undergo surgery or inability to undergo surgery or inability to administer intralesional medical therapy such as interferon alpha or 5-FU. Age 18 years and older. Size of lesions less than 2 cm Superficial and nodular form of BCC Multiple lesions

Intervention groups
Methylene blue 0.5mg/ml solution and formulated ointment are applied topically to the lesion every two days for a month and the lesion is photographed. If the wound improves and shrinks, the same procedure is continued until complete healing, and if there is no improvement after one month, standard methylene blue photodynamic therapy is applied for another month.

Main outcome variables
Wound healing rate based on dermoscopic results and clinical repair

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250630066310N1**
Registration date: **2025-07-30, 1404/05/08**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-30, 1404/05/08**
Update count: **0**

Registration date
2025-07-30, 1404/05/08

Registrant information

Name
Mahdi Razmara ferezghi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3843 7333

Email address
razmarafm@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-26, 1404/04/05

Expected recruitment end date
2026-06-26, 1405/04/05

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of formulated methylene blue basal cell carcinoma (BCC)

Public title
effect of formulated methylene blue basal cell carcinoma (BCC)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Informed and written consent of the patient to participate in the study. Diagnosis of basal cell carcinoma of the skin confirmed by pathology. Patient unwillingness to undergo surgery or inability to undergo surgery or inability to administer intralesional medical treatment such as interferon alpha or 5-FU. Age 18 years and older. Lesion size less than 2 cm. Superficial and nodular form of BCC Multiple lesions

Exclusion criteria:
Basal cell carcinoma of the skin of the morphea-like and nodular ulcerative type Pregnancy and lactation. History of serious drug-related complications. Failure to complete the course of treatment. Failure to refer for follow-up treatment. History of cardiovascular diseases. History of thromboembolic diseases. Radiotherapy treatment in the relevant area Contact with arsenic. Weak immunity. Presence of serious systemic disease. Having a history of allergy or sensitivity to methylene blue. Having a history of bleeding disorders or abnormal blood clotting. Having a history of severe skin disorders or inflammation in the treatment area

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

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
Dermatology clinic of Imam Reza hospital

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Approval date
2025-06-25, 1404/04/04

Ethics committee reference number
IR.MUMS.IRH.REC.1404.040

Health conditions studied

1

Description of health condition studied
Basal Cell Carcinoma

ICD-10 code
C44.310

ICD-10 code description
Basal cell carcinoma of skin of unspecified parts of face

Primary outcomes

1

Description
Primary Outcome of Complete Wound Repair After 2 Months of Treatment Initiation Based on Dermoscopic Results and Clinical Repair

Timepoint
Methylene blue 0.5mg/ml solution and formulated ointment are applied topically to the lesion every two days for a month and the lesion is photographed. If the wound improves and shrinks, the same procedure is continued until complete healing, and if there is no improvement after one month, standard methylene blue photodynamic therapy is applied for another month.

Method of measurement
Outcomes are evaluated by measuring changes in lesion size, examining tissue repair, clinical and dermoscopic imaging.

Secondary outcomes

1

Description
The secondary outcome of the absence of ulcer recurrence after 6 months of patient follow-up

Timepoint

After the four stages of treatment, wound repair ointment will be applied to speed up the healing process.

Method of measurement

Outcomes are evaluated by measuring changes in lesion size, examining tissue repair, clinical and dermoscopic imaging. Also, if the patient agrees, tissue sampling will be used to evaluate pathology.

Intervention groups

1

Description

Intervention group: Intervention group: Methylene blue 0.5mg/ml solution and formulated ointment are applied topically on the patient's BCC lesion every two days for a month and the lesion is photographed. If the wound improves and shrinks, the same procedure will continue until complete healing, and if there is no improvement after one month, standard methylene blue photodynamic therapy will be applied for another month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dermatology Clinic of Imam Reza Hospital

Full name of responsible person
Mahdi Razmara Farzaghi

Street address
Dermatology Clinic of Imam Reza Hospital

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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
Daneshgah street Ghoreyshi building

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TafaghodiM@mums.ac.ir

Grant name

Grant code / Reference number

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

No

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
Mahdi Razmara

Position
professor.Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mahdi Razmara

Position
Professor, Associate professor

Latest degree

Specialist

Other areas of specialty/work
Dermatology

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohammadali Kerachian

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more data

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not 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
Data of clinical trial in analysis will be published in an article after blinding patients' data

When the data will become available and for how long
Unlimited from publishing

To whom data/document is available
Researchers in medical universities

Under which criteria data/document could be used
Data are specific for this study and is not reusable

From where data/document is obtainable
Request by email to the corresponding author recorded in this registry Dr.Mahdi Razmara Email: razmarafn@mums.ac.irTel: +985138022031 Address: Dermatology department, Imam Reza hospital, Imam Reza hospital square, Avecina street, Imam Reza hospital square, Mashhad

What processes are involved for a request to access data/document
Sending a formal request with details of the needed information to the email of the person responsible for scientific inquiries. Then it will be responded to after one week by the person responsible for scientific inquiries.

Comments