

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Evaluation of the Efficacy of Topical Modified Sulfur Dioxide on the Treatment of Benign Skin Lesions; Moles, Warts and Seborrheic Keratosis

Protocol summary

Study aim

Evaluation of the efficacy of topical solution containing 80% sulfur dioxide, 10% extract of myrtus communis and 10% extract of saffron on the treatment of benign skin lesions; moles, warts and seborrheic keratosis.

Design

This study is a non-randomized clinical trial without a control group. patients are selected using convenience sampling. The minimum sample size is 64 according to previous studies (19 patients with moles, 25 warts and 20 seborrheic keratoses).

Settings and conduct

Among patients who visit the physician's office those whose skin lesions are confirmed by clinical examination are enrolled in the study. After obtaining written consent a punch biopsy is obtained prior to the treatment. After the treatment period (about three weeks later), another punch biopsy is obtained. Patients are visited in 4, 8, and 12 weeks later to determine the recurrence rate.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients whose skin lesions (Moles, Warts or Seborrheic Keratosis) are confirmed by a physician following a clinical examination. Exclusion criteria: Patient with suspected malignant lesions. Presence of wounds or other active skin disease.

Intervention groups

Intervention group: After type of the lesion is confirmed, a treatment solution containing 80% sulfur dioxide, 10% extract of myrtus communis and 10% extract of saffron is placed topically on the lesion by the physician. The solution is produced by Zojaj Darman Toos pharmaceutical company . If necessary, the treatment session is repeated with the presence of the physician. Patients are not charged for treatment, visits, or tests.

Main outcome variables

Lesion size; pathology report

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151230025772N7**

Registration date: **2020-04-04, 1399/01/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-04, 1399/01/16**

Update count: **0**

Registration date

2020-04-04, 1399/01/16

Registrant information

Name

Seyyed Abbas Zojaji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3711 2717

Email address

zojajia881@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Efficacy of Topical Modified Sulfur Dioxide on the Treatment of Benign Skin Lesions; Moles, Warts and Seborrheic Keratosis

Public title

Effect of Sulfur in treatment of Moles, Warts and Seborrheic Keratosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients whose skin lesions (Moles, Warts or Seborrheic Keratosis) are confirmed by a physician following a clinical examination.

Exclusion criteria:

Suspected of malignant lesions Presence of wounds or other active skin disease

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 64

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 Islamic Azad University - Mashhad Branch

Street address

Dr Shahinfar Medical Faculty, Sarab Alley., Imam Khomeimi Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

9187147578

Approval date

2019-08-26, 1398/06/04

Ethics committee reference number

IR.IAU.MSHD.REC.1398.231

Health conditions studied

1

Description of health condition studied

Mole (Melanocytic nevi)

ICD-10 code

D22

ICD-10 code description

Melanocytic nevi

2

Description of health condition studied

wart

ICD-10 code

B07

ICD-10 code description

Viral warts

3

Description of health condition studied

seborrheic keratosis

ICD-10 code

L82

ICD-10 code description

Seborrheic keratosis

Primary outcomes

1

Description

Size of the lesion

Timepoint

Baseline (before intervention), 3, 7, 11, and 15 weeks after treatment.

Method of measurement

Clinical examination

2

Description

Pathology report

Timepoint

Baseline (before intervention), 3, 7, 11, and 15 weeks after treatment.

Method of measurement

Pathology examination of the lesion`s punch biopsy by a specialist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After type of the lesion is confirmed, a treatment solution containing 80% sulfur dioxide, 10% extract of myrtus communis and 10% extract of saffron is placed topically on the lesion by the physician. The solution is produced by Zojaj Darman Toos pharmaceutical company . If necessary, the treatment session is repeated with the presence of the physician. Patients are not charged for treatment, visits, or tests.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farnoosh Bidouee`s Office

Full name of responsible person

Farnoosh Bidouee

Street address

Dr Bidouee`s Office, No. 758, Between Moalem 30 and 32, Moalem Blvd, Mashhad City.

City

Mashhad

Province

Razavi Khorasan

Postal code

9188996118

Phone

+98 51 3605 5668

Email

Fah22ba@yahoo.com

2

Recruitment center

Name of recruitment center

Farnoosh Bidouee`s Office 2

Full name of responsible person

Farnoosh Bidouee

Street address

Dr Bidouee`s Office, No. 834, Between Sanabad 58 and 60, Sanabad Street, Mashhad City.

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9185678577

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Fah22ba@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Saeed Abtahi

Street address

Shahinfar Faculty of Medicine, Imam Khomeini Ave, Mashhad

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IMRC@mshdiau.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Farnoosh Bidouee

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farnoosh Bidouee

Position

Non-Academic Specialist Physician

Latest degree

Specialist

Other areas of specialty/work

Traditional Medicine

Street address

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Farnoosh Bidouee

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Farnoosh Bidouee

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