

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating the safety (safety/harmlessness) and effectiveness of Sigol brand insect repellent spray in healthy volunteer

Protocol summary

Study aim

Evaluating the safety (safety/harmlessness) and effectiveness of Sigol brand insect repellent spray in healthy volunteer

Design

The study is a phase 2, two groups compared to control. The sample size is 10. The study was not randomized.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy in Tehran university of medical sciences, 10 healthy volunteers will be selected and enrolled in the study after signing consent form. 1 ml of Sigol insect repellent is sprayed on a forearm and 1 ml of ethanol solution 20% DEET is sprayed on the other forearm, after 30 minutes, the treated area is placed in a test cage, and it is exposed to mosquitoes for 3 minutes to measure the number of mosquito landings or exploration.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages 18 to 60, Signing consent form to participate in the study, Observing the study conditions and tendency to attend regular follow-up courses, Insensitivity of volunteers to the experimental herbal composition, Insensitivity or mild sensitivity to mosquito bites. Exclusion criteria: Documented sensitivity to formulation components, susceptibility to mosquito bites, active smokers

Intervention groups

1 ml of Sigol insect repellent a product of Akhavi Laboratory is sprayed on a forearm and after 30 minutes, the treated area is placed in a test cage, and it is exposed to mosquitoes for 3 minutes to measure the number of mosquito landings or exploration. Control group: 1 ml of ethanol solution 20% DEET is sprayed on the other forearm and after 30 minutes, the treated area is placed in a test cage, and it is exposed to mosquitoes for 3 minutes to measure the number of mosquito landings or exploration.

Main outcome variables

Estimated full protection time (Measurement of repellent application time up to the first mosquito landing or exploration)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150101020514N21**

Registration date: **2023-03-14, 1401/12/23**

Registration timing: **prospective**

Last update: **2023-03-14, 1401/12/23**

Update count: **0**

Registration date

2023-03-14, 1401/12/23

Registrant information

Name

Alireza Firooz

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 8190

Email address

firozali@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-19, 1402/01/30

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the safety (safety/harmlessness) and effectiveness of Sigol brand insect repellent spray in healthy volunteer

Public title

Evaluating the safety and effectiveness of Sigol insect repellent spray

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

Ages 18 to 60 Signing consent form to participate in the study Observing the study conditions and tendency to attend regular follow-up courses Insensitivity of volunteers to the experimental herbal composition Insensitivity or mild sensitivity to mosquito bites

Exclusion criteria:

Documented sensitivity to formulation components susceptibility to mosquito bites active smokers

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **10**

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 The Institute of Pharmaceutical Sciences of Tehran University of Medical Science

Street address

Unit 1-219, 2nd floor, The Institute of Pharmaceutical Sciences, Faculty of Pharmacy, 16 Azar Avenue

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2023-02-26, 1401/12/07

Ethics committee reference number

IR.TUMS.TIPS.REC.1401.123

Health conditions studied**1****Description of health condition studied**

Insect bite (nonvenomous)

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Estimated full protection time (Measurement of repellent application time up to the first mosquito landing or exploration)

Timepoint

A three-minute interval

Method of measurement

Using a digital camera

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 1 ml of Sigol insect repellent a product of Akhavi Laboratory is sprayed on a forearm and after 30 minutes, the treated area is placed in a test cage, and it is exposed to mosquitoes for 3 minutes to measure the number of mosquito landings or exploration.

Category

Prevention

2**Description**

Control group: 1 ml of ethanol solution 20% DEET is sprayed on the other forearm and after 30 minutes, the treated area is placed in a test cage, and it is exposed to mosquitoes for 3 minutes to measure the number of mosquito landings or exploration.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for research and training in skin diseases and leprosy, Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Street address

415, Taleghani Avenue.

City

Tehran

Province

Tehran

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1416613675

Phone

+98 21 8897 2220

Email

dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Akhavi laboratory

Full name of responsible person

Farid Akhavi

Street address

Unit 8, No.17, Tavanir Street, Valiasr Street

City

Tehran

Province

Tehran

Postal code

1434875419

Phone

+98 21 8879 8126

Email

info@akhavilab.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Akhavi laboratory

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

Tehran University of Medical Sciences

Full name of responsible person

Aniseh Samadi

Position

Manger of clinical study unit

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

Street address

No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Khamesipour

Position

Professor of Immunoparasitology

Latest degree

Ph.D.

Other areas of specialty/work

Parasitology

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+98 21 8897 2220

Email

alikhamesipour@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Clinical trial

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No 415, Taleqani Street

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable