Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 and1 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

Postal code
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 traial

Street address

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City

Tehran

Province

Tehran

Postal code

1416613675

Phone

+98 21 8897 2220

Email

dermalab@tums.ac.ir

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