

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Investigation and comparison of the effect of ginger and sesame oils on resistance against frostbite in military personnel

Protocol summary

Study aim

Investigation of the effect of ginger and sesame oils on resistance against frostbite in military personnel

Design

The study includes double-blinded randomized controlled interventional trials (phase 1). Participants will be randomly allocated into 3 groups (of 20 subjects each) including control, sesame and ginger groups.

Settings and conduct

The cold-protective effect of topical application of ginger and sesame oils will be investigated on forty-two young men (control, ginger and sesame groups) using cold-water immersion trials (12°C and 5°C water) in the physiology laboratory of Aja University of medical sciences. The study is double-blinded in which neither the researcher nor the participants know what they were getting. The subjects of the oil groups will be asked to rub the oils on their hands up to the wrist and wait for 5 minutes before the immersion. The index finger skin temperature, systolic and diastolic blood pressure, pulse rate, the beginning of the pain sensation, pain and thermal sensation will be recorded before and immediately after intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: male participants aged 18-30 year-old
Exclusion criteria: Raynaud's syndrome; peripheral vascular disease; inflammatory arthritis; heart diseases; high blood pressure; malignancy; previous hand or finger transplantation

Intervention groups

The subjects of the ginger and sesame oil groups will be asked to rub the oils on their hands up to the wrist. The control group receives no treatment.

Main outcome variables

Index finger skin temperature; systolic and diastolic blood pressure; pulse rate; the beginning of the pain sensation; pain sensation; thermal sensation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200102045988N1**

Registration date: **2020-02-25, 1398/12/06**

Registration timing: **prospective**

Last update: **2020-02-25, 1398/12/06**

Update count: **0**

Registration date

2020-02-25, 1398/12/06

Registrant information

Name

Seyed Mojtaba Kasaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3353 6365

Email address

mkasae2819@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-05, 1398/12/15

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation and comparison of the effect of ginger and sesame oils on resistance against frostbite in military personnel Public title The effect of ginger and sesame oils on resistance against frostbite Purpose Prevention Inclusion/Exclusion criteria Inclusion criteria: Male volunteers aged 18-30 year-old Exclusion criteria: Raynaud's syndrome Peripheral vascular disease Inflammatory arthritis Heart diseases High blood pressure Malignancy Previous hand or finger transplantation Age From 18 years old to 30 years old Gender Male Phase 3 Groups that have been masked • Participant • Investigator Sample size Target sample size: 60 Randomization (investigator's opinion) Randomized Randomization description Allocation sequence will be generated using a computer program. In this software, a code will be assigned to each group (Zingiber oil, Sesame oil and Control) and sample size will be written. Randomization will be done in blocks of three. Since the generated sequence is produced by research assistant, the main researcher is not informed of the assigned codes to the groups. The generated codes will be written on papers, then concealed sequentially inside opaque lookalike containers. Blinding (investigator's opinion) Double blinded Blinding description The study is double-blinded in which neither the researcher nor the participants know about the received treatment. The research assistant, who generates the allocation sequence, will conceal the code of related intervention inside opaque lookalike containers. The participants will get into the study (block size 3). The first participant will randomly choose one of the containers. Then, the other two participants will do the same and choose between the left containers. After choosing one of the containers by the participant, research assistant will read the concealed intervention code inside the container. Then, research assistant will give the related intervention to the main researcher to try it on the participant. Placebo Not used Assignment	Parallel Other design features Secondary Ids empty Ethics committees 1 Ethics committee Name of ethics committee Ethics committee of Artesh University of Medical Sciences Street address Ethics committee of Artesh University of Medical Sciences, West Fatemi St., Etemadzadeh St., Tehran City Tehran Province Tehran Postal code 1411718541 Approval date 2018-06-18, 1397/03/28 Ethics committee reference number IR.AJAUMS.REC.1397.019 Health conditions studied 1 Description of health condition studied The effect of ginger and sesame oils on resistance against frostbite ICD-10 code T33.521 ICD-10 code description Superficial frostbite of right hand Primary outcomes 1 Description Index finger skin temperature Timepoint Before and immediately after intervention Method of measurement Infrared thermometer 2 Description Systolic blood pressure Timepoint Before and immediately after intervention Method of measurement Digital sphygmomanometer
--	---

3

Description

Diastolic blood pressure

Timepoint

Before and immediately after intervention

Method of measurement

Digital sphygmomanometer

4

Description

Pulse rate

Timepoint

Before and immediately after intervention

Method of measurement

Digital sphygmomanometer

Secondary outcomes

1

Description

Beginning of the pain sensation

Timepoint

After intervention (during immersion)

Method of measurement

Stopwatch

2

Description

Pain sensation

Timepoint

At the end of the immersion

Method of measurement

Eleven-point scale

3

Description

Thermal sensation

Timepoint

At the end of the immersion

Method of measurement

nine-point scale

Intervention groups

1

Description

Intervention group 1: ginger oil (20 drops or 0.75 cc using a pipette) will be rubbed on the right hand before immersion in the cold water. Ginger oil extraction method: Standard protocol in traditional medicine using sesame oil

Category

Prevention

2

Description

Intervention group 2: sesame oil (20 drops or 0.75 cc using a pipette) will be rubbed on the right hand before immersion in the cold water. Manufacturer: Niri Organic Yazd Company

Category

Prevention

3

Description

Control group: immersion of the right hand in the cold water without application of the oils

Category

Prevention

Recruitment centers

1

Recruitment center**Name of recruitment center**

Artesh University of Medical Sciences

Full name of responsible person

Nafiseh Hosseini Yekta

Street address

West Fatemi St., Etemadzadeh St., Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone**Email**

nhyekta@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Artesh University of Medical Sciences

Full name of responsible person

Saeed Soleiman Meigooni

Street address

West Fatemi St., Etemadzadeh St., Tehran

City

Tehran

Province

Tehran

Postal code

1411718541

Phone**Email**

dr.saeed.meigooni@gmail.com

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

Yes

Title of funding source

Artesh 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
Artesh University of Medical Sciences
Full name of responsible person
Seyed Mojtaba Kasaei
Position
Conscript
Latest degree
Master
Other areas of specialty/work
Marine Biology
Street address
No. 151, Farzaneh Alley, Shohadaye Gomnam Blvd.,
Rasht City
City
Rasht
Province
Guilan
Postal code
4155813717
Phone
+98 13 3353 6365
Fax
Email
mkasaee2819@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Seyed Mojtaba Kasaei
Position
Conscript
Latest degree
Master
Other areas of specialty/work
Marine Biology
Street address
No. 151, Farzaneh Alley, Shohadaye Gomnam Blvd.,
Rasht City
City
Rasht

Province
Guilan
Postal code
4155813717
Phone
+98 13 3353 6365
Fax
Email
mkasaee2819@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Seyed Mojtaba Kasaei
Position
Conscript
Latest degree
Master
Other areas of specialty/work
Marine Biology
Street address
No. 151, Farzaneh Alley, Shohadaye Gomnam Blvd.,
Rasht City
City
Rasht
Province
Guilan
Postal code
4155813717
Phone
+98 13 3353 6365
Fax
Email
mkasaee2819@gmail.com

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