

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of antiseptics effect of herbal solution of A-S14-1 on hand skin

#### Protocol summary

##### Summary

In this clinical trial, an alcohol free skin's friend herbal solution of A-S14-1 will evaluate as a disinfectant without any above mentioned chemical compounds. The aim of the study is to evaluate the disinfecting effects of herbal solution of A-S14-1 on hand skin of 20 men and women volunteers as a before and after study on the basis of EN12791 method. Inclusion criteria included short and clean nails, lack of use of ointments, medications or antimicrobial soap for at least a week before the intervention. Exclusion criteria will pregnant women, any cuts, wounds, abrasions on hands skin and skin diseases. Effect of herbal solution of A-S14-1 on microbial count of fingers tips will compare before and after washing with the solution as EN12791 procedure. Bacterial count before and after will compare as the main outcome of variables.

#### General information

##### Acronym

Spray A-S14-1

##### IRCT registration information

IRCT registration number: **IRCT2016020726409N1**

Registration date: **2016-03-27, 1395/01/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-03-27, 1395/01/08

##### Registrant information

###### Name

Parviz Owlia

###### Name of organization / entity

Shahed University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5522 8800

###### Email address

owlia@shahed.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Pishgaman Armaghan Aftab Company

###### Expected recruitment start date

2016-01-20, 1394/10/30

###### Expected recruitment end date

2016-03-05, 1394/12/15

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Evaluation of antiseptics effect of herbal solution of A-S14-1 on hand skin

###### Public title

Evaluation of Herbal Spray as hands Antiseptic

###### Purpose

Prevention

###### Inclusion/Exclusion criteria

Inclusion criteria: Fingernails should be short and clean; Non-use of ointments, medications or antimicrobial soap for at least a week before the interventions Exclusion criteria: Pregnant women; There are cuts, wounds, abrasions on the skin of the hands; The risk of skin disease

###### Age

From **18 years** old to **100 years** old

###### Gender

Both

###### Phase

N/A

###### 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

### 1

#### Registry name

ND

#### Secondary trial Id

ND

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahed University, Deputy of Research

##### Street address

Behesht-Zahra, Khaliije-Fars Freeway, Tehran

##### City

Tehran

##### Postal code

3319118651

#### Approval date

2016-01-19, 1394/10/29

#### Ethics committee reference number

IR.Shahed.REC.1394.68

## Health conditions studied

### 1

#### Description of health condition studied

Topical Agent

#### ICD-10 code

Y56.9

#### ICD-10 code description

Topical agent, unspecified

## Primary outcomes

### 1

#### Description

Basic Microbial count

#### Timepoint

Before Antisepsis by studied herbal solution

#### Method of measurement

Volunteers wash their hands with liquid normal soap for a minute and then rinse and drying laundry, The fingertips of both hands will rub for 1 minute in a petri dish containing 10 ml of TSB. Then, 1 and 0.1 ml of the liquid will take and will culture on petri dishes containing TSA (with a glass rod head tilt). In addition, from the fluid, one-tenth dilution in TSB was prepared and 0.1 ml will culture on TSA. If necessary, microbial count will continue to further dilutions in a pour-plate method. All samples will incubate at a temperature of  $37 \pm 1$  for 48-24 hours and then cfu / ml.

### 2

#### Description

Microbial count immediately after antisepsis by studied herbal solution

#### Timepoint

immediately after antisepsis by studied herbal solution

#### Method of measurement

Antisepsis of both hands will carry out by 3 ml of A-S14-1 solution and rubbing. If necessary, an additional 3 ml will add. As described for basic Microbial count, the method will accomplish on randomly selected hand after 3 minutes antisepsis by studied solution. The other hand will cover with a sterile surgical glove.

## Secondary outcomes

### 1

#### Description

Microbial count 3 hours after antisepsis by studied herbal solution

#### Timepoint

3 hours after antisepsis by studied herbal solution

#### Method of measurement

After 3 hours the glove from hand will remove and microbial count will perform as earlier mentioned method

## Intervention groups

### 1

#### Description

Effect of herbal solution A-S14-1 product of Pishgaman Armaghan Aftab Company on microbial count of fingers tips will compare before and after washing with the solution as EN12791 procedure. The herbal solution of A-S14-1 is compatible with skin, without any alcohol and chemicals such as chlorinated compounds, silver nanoparticles, tetravalent ammonium compounds, Triclosan etc. Antisepsis of both hands will carry out by 3 ml of A-S14-1 solution and rubbing. If necessary, an additional 3 ml will add. As described for basic Microbial count, the method will accomplish on randomly selected hand after 3 minutes antisepsis by studied solution. The other hand will cover with a sterile surgical glove.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Molecular Microbiology Research Center, Shahed University

**Full name of responsible person**

Professor Parviz Owlia

**Street address**

Research Centers of Shahed University, No.1471, First Floor, North Kargar St., Tehran, Iran

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Pishgaman Armaghan Aftab Company

**Full name of responsible person**

Ghasem Habibi Dehfooli

**Street address**

No. 14, Molaem, Besharat St, Arak, Iran

**City**

Arak

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

Yes

**Title of funding source**

Pishgaman Armaghan Aftab Company

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Pishgaman Armaghan Aftab Company

**Full name of responsible person**

Ghasem Habibi Dehfooli

**Position**

Chairman of the Board

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*