

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison of the effect of 5% formalin solution and anti-wart lotion (combination of salicylic acid 16.7% and lactic acid 16.7% in flexible collodion) in the treatment of wart

#### Protocol summary

##### Study aim

Comparison of the effect of Formalin 5% solution and Anti-wart lotion (salicylic acid 16.7% and lactic acid 16.7%) in the treatment of wart

##### Design

Clinical trial with parallel, randomized groups; Phase 3 trial; on 60 people who went to the dermatology clinic of Imam Khomeini Hospital in Ahwaz.

##### Settings and conduct

The field of the study: Dermatology clinic of Imam Khomeini Hospital in Ahwaz

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of plantar wart or common wart in the hands and feet. Exclusion criteria: Patients with a history of formaldehyde allergy; pregnancy or lactation; any treatment of wart in the last two weeks; any severe systemic disease; patients who also have other skin conditions such as lichen planus, psoriasis or eczema in the site of wart lesions; inability to cooperate with topical medications due to young age or sensory impairment.

##### Intervention groups

Intervention group 1: In formalin group, lesions were soaked with formalin 5% solution in shallow dish for 15-20 minutes twice a day, and if the soaking method was difficult, formalin-soaked cotton was placed on the wart lesions with an adhesive tape for 15-20 minutes. The duration of treatment was 8 weeks and the response to treatment was evaluated every four weeks. Intervention group 2: In lotion group, patients were treated with anti-wart lotion (containing 16.7% salicylic acid and 16.7% acetic acid) twice a day for 8 consecutive weeks. The solution was applied to the wart lesions by a small brush and then were covered with an adhesive tape for 15-20 minutes. The treatment lasted 8 weeks and the response to treatment was evaluated every four weeks

##### Main outcome variables

Warts count change

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200530047603N1**

Registration date: **2020-06-22, 1399/04/02**

Registration timing: **retrospective**

Last update: **2020-06-22, 1399/04/02**

Update count: **0**

##### Registration date

2020-06-22, 1399/04/02

##### Registrant information

##### Name

Simin Mansorian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3292 1837

##### Email address

mansorian\_s@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-12, 1398/04/21

##### Expected recruitment end date

2019-11-30, 1398/09/09

##### Actual recruitment start date

2019-07-12, 1398/04/21

##### Actual recruitment end date

2019-11-30, 1398/09/09

**Trial completion date**

2020-03-09, 1398/12/19

**Scientific title**

Comparison of the effect of 5% formalin solution and anti-wart lotion (combination of salicylic acid 16.7% and lactic acid 16.7% in flexible collodion) in the treatment of wart

**Public title**

The effect of formalin in the treatment of wart

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diagnosis of plantar wart and common wart in the hands and feet

**Exclusion criteria:**

Patients with a history of formaldehyde allergy  
Immunodeficiency Severe dermatitis Diabetes Pregnancy or lactation History of respiratory illnesses such as asthma Any treatment for wart in the last two weeks  
Taking immunosuppressive drugs Any severe systemic disease Patients with peripheral vascular disorder  
Patients with peripheral neuropathy Patients who also have other skin conditions such as lichen planus, psoriasis or eczema in the site of wart lesions Inability to cooperate in using topical drugs due to young age or sensory impairment

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Individuals are divided into two groups based on the block randomization method. Blocks of size 4 have been used for this purpose. A random sequence based on this method has been extracted from Sealedenvelope.com.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz University of Medical Sciences

**Street address**

Vice Chancellor for Research; Ahvaz Jundishapur University of Medical Sciences; Golestan boulevard

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6193673166

**Approval date**

2019-07-12, 1398/04/21

**Ethics committee reference number**

IR.AJUMS.REC.1398.287

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

Wart

**ICD-10 code**

B07

**ICD-10 code description**

Viral warts

**Primary outcomes****1****Description**

Wart count change

**Timepoint**

Before intervention and then every 4 weeks during intervention and three months after the end of the treatment

**Method of measurement**

By counting wart number

**Secondary outcomes****1****Description**

Dryness

**Timepoint**

Every 4 weeks during intervention

**Method of measurement**

Questionnaire

**2****Description**

Erythema

**Timepoint**

Every 4 weeks during intervention

**Method of measurement**

Questionnaire

**3****Description**

Fissuring

**Timepoint**

Every 4 weeks during intervention

**Method of measurement**

Questionnaire

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

Intervention group 1: In formalin group, lesions were soaked with formalin 5% solution in shallow dish for 15-20 minutes twice a day, and if the soaking method was difficult, formalin-soaked cotton was placed on the wart lesions with an adhesive tape for 15-20 minutes. The duration of treatment was 8 weeks and the response to treatment was evaluated every four weeks.

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2: In lotion group, after rubbing vaseline on the healthy skin around the wart lesions, patients applied the anti-wart lotion with a small brush to the lesions and then covered them with an adhesive tape for 15- 20 minutes. The duration of treatment was 8 weeks and the response to treatment was evaluated every four weeks.

**Category**

Treatment - Drugs

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

Dermatology department; Ahvaz Emam khomeini hospital

**Full name of responsible person**

Simin Mansorian

**Street address**

Azadegan street

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715794

**Phone**

+98 61 3292 1837

**Email**

mansorian\_s@yahoo.com

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

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr.Mohammad Badavi

**Street address**

Deputy of Research, Ahvaz Jundishapur University of Medical Sciences, Golestan boulevard

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715794

**Phone**

+98 61 3373 8383

**Email**

mbadavi@ajums.ac.ir

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Simin Mansorian

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

Imam Khomeini Hospital, Azadegan avenue

**City**

Ahvaz

**Province**

Khouzestan  
**Postal code**  
6193673166  
**Phone**  
+98 61 3292 1837  
**Email**  
Mansorian\_s@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Simin Mansorian  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
Imam Khomeini Hospital, Azadegan avenue  
**City**  
Ahvaz  
**Province**  
Khouzestan  
**Postal code**  
6193673166  
**Phone**  
+98 61 3292 1837  
**Fax**  
**Email**  
mansorian\_s@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**

Simin Mansorian  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
Imam Khomeini Hospital, Azadegan avenue  
**City**  
Ahvaz  
**Province**  
Khouzestan  
**Postal code**  
6193673166  
**Phone**  
+98 61 3292 1837  
**Fax**  
**Email**  
mansorian\_s@yahoo.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