

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Hypochlorite Sodium 0.005% versus placebo in treatment of mild to moderate Acne; A randomized double blind clinical control

#### Protocol summary

##### Study aim

Determining the effect of topical Hypochlorite sodium 0.005% versus placebo in treatment of mild to moderate acne

##### Design

Randomized double blind Clinical Trial

##### Settings and conduct

In dermatology clinic of Shahid Faghihi hospital, the patients were assigned to receive Hypochlorite sodium 0.005% or placebo to be administered topically on each side of their face three times a day for one month. Hypochlorite sodium 0.005% and placebo were applied randomly on each side of the patients' faces. On the other hand, the patients were not aware of the type of solution (placebo or Hypochlorite sodium 0.005%) applied for them. In addition to patients, dermatologist and the recorder person were blind about the solution applied for each patient.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with mild to moderate Acne Vulgaris diagnosed by dermatologist  
Exclusion criteria: Patients with symptoms such as secondary Acne caused by lactation  
Dermatology condition in addition to Acne  
Patients who had taken drugs such as Isotretinoin or systemic, topical antibiotics within the last two months  
Allergy to Hypochlorite Sodium

##### Intervention groups

Intervention group: The patients received Hypochlorite sodium 0.005% randomly to be administered topically on the right or left side of their faces three times a day for one month. Control group: The patients received placebo (distilled water) randomly to be administered topically on the right or left side of their faces three times a day for one month. The patients were not aware of the type of solution (placebo or Hypochlorite sodium 0.005%) applied for them. In addition to patients, dermatologist and the recorder person were both blind about the solution applied for each side of patient's face.

##### Main outcome variables

Evaluation of Acne remission on the basis of changes in the number of papules and pustules

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200701047976N1**

Registration date: **2020-07-14, 1399/04/24**

Registration timing: **prospective**

Last update: **2020-07-14, 1399/04/24**

Update count: **0**

##### Registration date

2020-07-14, 1399/04/24

##### Registrant information

##### Name

Nafiseh Todarbary

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3870 5548

##### Email address

ntodarbary@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-22, 1399/05/01

##### Expected recruitment end date

2020-09-22, 1399/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Hypochlorite Sodium 0.005% versus placebo in treatment of mild to moderate Acne; A randomized double blind clinical control

**Public title**

Effect of Hypochlorite Sodium 0.005% in treatment of Acne

**Purpose**

Treatment

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

Patients with mild to moderate Acne Vulgaris diagnosed by dermatologist

**Exclusion criteria:**

Patients with symptoms such as secondary Acne caused by lactation Dermatology condition in addition to Acne  
Patients who had taken drugs such as Isotretinoin or systemic/topical antibiotics within the last two months  
Allergy to Hypochlorite Sodium

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

We used block randomization method. Our sample includes 40 patients which was divided into 10 blocks with 4 patients in each one. With random number table, our sample was divided into A and B groups and the data was written on the paper and randomization was done by random number table manually. Group A received Hypochlorite sodium 0.005% on the right side of their face and group B received that on the left side of their face; concurrently, group A received placebo on the left side of their face and group B received that on the right side of their face.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Although Hypochlorite Sodium and placebo(distilled water) were both put into the same white bottles; each bottle has specific code showing its content. Only the pharmacist is aware about these codes. During study, both dermatologist and patients were blind about using Hypochlorite sodium and placebo on each side of patients' faces.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of Shiraz University of Medical Sciences

**Street address**

School medicine of Shiraz, Emam Hosein Square, Zand Blvd

**City**

Shiraz

**Province**

Fars

**Postal code**

7134845794

**Approval date**

2018-12-31, 1397/10/10

**Ethics committee reference number**

IR.SUMS.MED.REC.1397.413

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

Acne Vulgaris

**ICD-10 code**

L70.0

**ICD-10 code description**

Acne vulgaris

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

Evaluation of Acne remission on the basis of changes in the number of Papules and Pustules

**Timepoint**

Initiation of study(before starting the treatment), 14 days and 28 days after starting the treatment

**Method of measurement**

Counting the number of Papules and Pustules

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: Solution of Hypochlorite sodium 0.005% was prepared by pharmacist from Hypochlorite sodium 6%. In this study, the concentration of solution was determined according to the formulation used in previous studies. On the other hand, higher concentrations increase the possibility of skin damage. Although Hypochlorite sodium and placebo(distilled water) were both put into the same white bottles; each bottle has specific code showing its content. Only the pharmacist is aware about these codes. The patients received Hypochlorite sodium 0.005% administered topically on the right or left side of their face three times a day for one month. Hypochlorite sodium 0.005% was applied randomly on each side of the patients' faces. The patients were not aware of the type of solution (placebo or Hypochlorite sodium 0.005%) applied for them. In addition to patients, dermatologist and the recorder person were both blind about the solution applied for each side of patient's face.

### Category

Treatment - Drugs

## 2

### Description

Control group: The patients received placebo(distilled water)administered topically on the right or left side of their faces three times a day for one month. The placebo was applied randomly on each side of the patients' faces. The patients were not aware of the type of solution (placebo or Hypochlorite sodium 0.005%) applied for them. In addition to patients, dermatologist and the recorder person were both blind about the solution applied for each side of patient's face.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Faghihi hospital

##### Full name of responsible person

Azadeh Dorostkar

##### Street address

Next to the School medicine of Shiraz, Emam Hosein Square, Zand Blvd

##### City

Shiraz

##### Province

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7134844119

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##### Email

faghihihsp@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Mehdi Ghahartars

##### Street address

School medicine of Shiraz, Emam Hosein Square, Zand Blvd

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##### Phone

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mghahar@sums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Maryam Hadibarhaghtalab

##### Position

Dermatology resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dermatology

##### Street address

Maryam Barhaghtalab (Seifi), 2nd Floor, 143 Plaque, Zanbagh 9 Alley, Farhangshahr Blvd

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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Maryam Hadibarhaghtalab

**Position**

Dermatology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Nafiseh Todarbary

**Position**

Medical Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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**Phone**

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**Email**

ntoodarbary@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