

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Determination of the Effect of Oral zinc therapy on the Treatment of Acne vulgaris in Patients with Grade 2 and 3 Acne vulgaris

#### Protocol summary

##### Study aim

Determine the effect of oral zinc therapy in Acne Vulgaris disease

##### Design

Clinical trial with a control group, one blind, randomized

##### Settings and conduct

In this study 100 patients with Acne Vulgaris referred to the clinic Khalij-e-Fars of Bushehr 2 in the year 2017-2018, based on the inclusion and exclusion criteria, were randomly allocated in two groups of intervention and control are included. The control group received routine acne vulgaris treatment alone (including 1% localized clindamycin gel and 1% salicylic acid topical), and the intervention group received routine Acne Vulgaris plus 60 mg daily oral zinc sulfate. Patients are treated for 12 weeks. At the start of the treatment and every visit, the doctor will estimate the number of lesions and at the end of the treatment period, the rate of recovery and possible side effects in both groups of the improvement degree. These data provided in the checklist for information purposes by the researcher. Data will be analyzed by a statistician without knowing the type of patient treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 2nd and 3rd grade of Acne Vulgaris patients based on Pillsburg classification  
Exclusion criteria: The patients with Gastrointestinal disorder  
The pregnant patients and breast feeding mothers  
Using other topical and oral anti Acne drugs  
Patients with Grade 1 and 4 Acne Vulgaris  
Female patients with hormonal disorders  
Patients with oral Isotretinoin in the last 3 months  
In case of no timely referral of the patient to evaluate the treatment  
In case of intolerance to the digestive tract by the patient

##### Intervention groups

Giving 60 mg oral Zinc daily to 50 patients with Acne Vulgaris and examining patients every 2 weeks for recovery. Choosing 50 Patients with Acne Vulgaris Without oral Zinc tablets

#### Main outcome variables

Reduce or eliminate signs and symptoms of Acne Vulgaris disease

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190505043485N1**

Registration date: **2019-06-01, 1398/03/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-06-01, 1398/03/11**

Update count: **0**

##### Registration date

2019-06-01, 1398/03/11

##### Registrant information

##### Name

Sakineh Heidari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3727 9123

##### Email address

aminboldaji@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-11, 1398/02/21

##### Expected recruitment end date

2019-06-11, 1398/03/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Determination of the Effect of Oral zinc therapy on the Treatment of Acne vulgaris in Patients with Grade 2 and 3 Acne vulgaris

**Public title**  
Evaluation of oral zinc therapy in Acne Vulgaris disease

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
2nd and 3rd grade of Acne Vulgaris patients depends on Pillsburg classification  
**Exclusion criteria:**  
The patients with Gastrointestinal disorder The pregnant patients and breast feeding mothers Using other topical and oral anti Acne drugs Patients with Grade 1 and 4 Acne Vulgaris Female patients with hormonal disorders Patients with oral Isotretinoin in the last 3 months

**Age**  
From **15 years** old to **40 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Data analyser

**Sample size**  
Target sample size: **100**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Among the patients with Acne Vulgaris referred to the Khalij-e-Fars clinic of Bushehr, who are eligible for inclusion in the study, 100 patients are randomly selected and divided into Intervention and control groups by block method, each group Includes 50 patients.To do this, 50 sealed envelopes are used as envelopes A and 50 sealed envelopes as B envelopes. People who select envelope A fall into the control group and those who choose B envelope fall into the intervention group

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Data will be analyzed by a statistician without knowing the type of patient treatment

**Placebo**  
Not used

**Assignment**  
Other

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Ethics committee of Boushehr University of Medical Sciences

**Street address**

Salman Farsi st

**City**

Boushehr

**Province**

Boushehr

**Postal code**

7514633341

**Approval date**

2019-05-08, 1398/02/18

**Ethics committee reference number**

IR.BPUMS.REC.1398.023

## 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**

Reduce in number of Acne

**Timepoint**

Evaluation the number of Acne in 14 days

**Method of measurement**

Observational

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Patients in the intervention group in addition to the routine treatment of Acne Vulgaris (containing 1% topical Clindamycin gel and 1% topical Salicylic Acid gel) will receive Zinc Sulfate tablets 60 mg daily orally as a therapeutic intervention for 3 months

**Category**

Treatment - Drugs

## 2

### Description

Control group: Patients in the control group received only routine Acne Vulgaris treatment without any extra work

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

The Khalij e Fars hospital

**Full name of responsible person**

Doctor Marziyeh Afrouzandeh

**Street address**

Taleqani blvd

**City**

Boushehr

**Province**

Boushehr

**Postal code**

7517933755

**Phone**

+98 77 3345 5390

**Email**

mpgh@bpums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Boushehr University of Medical Sciences

**Full name of responsible person**

doctor Gholamreza Khamisi por

**Street address**

Salman farsi st

**City**

Boushehr

**Province**

Boushehr

**Postal code**

7514633341

**Phone**

+98 77 3332 2081

**Email**

Khamisipoor@bpums.ac.ir

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

Yes

**Title of funding source**

Boushehr 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**

Boushehr University of Medical Sciences

**Full name of responsible person**

Doctor Marziyeh Afrouzandeh

**Position**

professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Taleqani Blvd

**City**

Boushehr

**Province**

Boushehr

**Postal code**

7517933755

**Phone**

+98 77 3345 5490

**Email**

marzieh642004@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Boushehr University of Medical Sciences

**Full name of responsible person**

Doctor Marziyeh Afrouzandeh

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Taleqani Blvd

**City**

Boushehr

**Province**

Boushehr

**Postal code**

7517933755

**Phone**

+98 77 3345 5390

**Email**

Marzieh642004@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Boushehr University of Medical Sciences

**Full name of responsible person**

doctor Marzieh Afrouzandeh

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Taleqani Blvd

**City**

Boushehr

**Province**

Boushehr

**Postal code**

7517933755

**Phone**

+98 77 2234 5390

**Email**

Marzieh642004@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