

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Effectiveness of Zinc Supplementation on Clinical Signs of Plaque Type Psoriasis Patients with Skin Involvement Under 20%

#### Protocol summary

##### Study aim

Effectiveness of zinc supplementation on clinical signs (severity of itching, erythem, scaling, induration and surface area of plaques) of patients with plaque type psoriasis with skin involvement under 20%.

##### Design

In this Clinical Trial estimated number of patients is 40 that they will be classified with simple randomization method in 2 groups of intervention and control group each include 20 patients and these 2 parallel groups will enter phase 3rd of trial with double blinded method.

##### Settings and conduct

About 100 of patients who refer to the Dermatology Clinic of Ardabil Imam Reza Hospital will be sent for screening of serum zinc level and patients who has serum zinc deficiency will enter the Clinical Trial. At first a list of clinical signs of every patient will record then the patients will be classified in 2 groups of Intervention and Control group with simple randomization method. During the intervention period all patients of both group will be followed up about changes in clinical signs every two weeks and after intervention period, they will be followed up every month till 3 month. Also during the intervention both patients and researchers (dermatologist and student) will be blind of medication the patients take ( zinc supplement or placebo).

##### Participants/Inclusion and exclusion criteria

Entrance: Patients with Plaque Type Psoriasis with skin involvement under 20% , Serum Zinc Deficiency; Exit: Patients with Gastrointestinal problems.

##### Intervention groups

Intervention group will receive 220 mg zinc sulfate supplement once daily with topical urea eucerine emollient cream 3 times a day for 1 month and Control group will receive placebo once daily with topical urea eucerine emollient cream 3 times a day for 1 month.

##### Main outcome variables

severity of itching, erythema , scaling, body surface area and induration of plaques

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191022045186N1**

Registration date: **2019-12-02, 1398/09/11**

Registration timing: **retrospective**

Last update: **2019-12-02, 1398/09/11**

Update count: **0**

##### Registration date

2019-12-02, 1398/09/11

##### Registrant information

##### Name

Romina Behboudi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3352 0045

##### Email address

r.behboudi@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-22, 1398/07/30

##### Expected recruitment end date

2019-11-06, 1398/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of Zinc Supplementation on Clinical Signs of Plaque Type Psoriasis Patients with Skin Involvement Under 20%

**Public title**

Effect of Zinc in treatment of Psoriasis

**Purpose**

Treatment

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

Plaque Type Psoriasis Patients with Skin Involvement Under 20% with Serum Zinc Deficiency

**Exclusion criteria:**

Patients with Gastrointestinal Problems and Malabsorption Syndrome

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: 40

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization Method: Simple Randomization  
Randomization Schedule: Random Number Table  
Randomization Unit: Individual ( student and dermatologist)

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this process patients, researchers ( medical student and the dermatologist doctor) and evaluators of consequence ( patients themselves, medical student and dermatologist ) are blind and none of them doesn't know which medication the patients are taking ( zinc supplement or placebo)

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of Ardabil University of Medical

Sciences

**Street address**

Ardabil University of Medical Sciences, Daneshgah Square, Daneshgah Avenue, Ardabil Town

**City**

Ardabil

**Province**

Ardabil

**Postal code**

5618985991

**Approval date**

2019-10-22, 1398/07/30

**Ethics committee reference number**

IR.ARUMS.REC.1398.382

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

Plaque Type Psoriasis with Skin Involvement Under 20%

**ICD-10 code**

L41.3

**ICD-10 code description**

Small plaque parapsoriasis

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

Difference in itching of plaques

**Timepoint**

Before intervention, 14, 30, 60, 90, 120 days after intervention

**Method of measurement**

Severity mentioned by patient according to BSA and PASI indexes

**2****Description**

Difference in erythem of plaques

**Timepoint**

Before intervention, 14, 30, 60, 90, 120 days after intervention

**Method of measurement**

Severity mentioned by patient according to BSA and PASI indexes

**3****Description**

Difference in scaling of plaques

**Timepoint**

Before intervention, 14, 30, 60, 90, 120 days after intervention

**Method of measurement**

Severity mentioned by patient according to BSA and PASI indexes

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##### **Description**

Difference in surface area of plaques

##### **Timepoint**

Before intervention, 14, 30, 60, 90, 120 days after intervention

##### **Method of measurement**

Severity mentioned by patient according to BSA and PASI indexes

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##### **Description**

Difference in induration of plaques

##### **Timepoint**

Before intervention, 14, 30, 60, 90, 120 days after intervention

##### **Method of measurement**

Severity mentioned by patient according to BSA and PASI indexes

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

##### **Description**

Intervention group: The intervention group will take 220mg zinc sulfate capsule once daily with topical urea eucerine emollient cream three times a day on plaques till one month.

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

Control group: The control group will take placebo once daily with topical urea eucerine emollient cream three times a day on plaques till one month.

##### **Category**

Placebo

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Dermatology Clinic of Emam Reza Hospital

###### **Full name of responsible person**

Dr Majid Rostami Moghaddam

###### **Street address**

Near to Islamic Azad University of Ardabil, Basij Square, Ardabil Town

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### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Ardabil University of Medical Sciences

###### **Full name of responsible person**

Dr Hale Valizadeh Haghghi

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##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Ardabil University of Medical Sciences

##### **Proportion provided by this source**

70

##### **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**

Ardabil University of Medical Sciences

###### **Full name of responsible person**

Romina Behboudi

###### **Position**

Medical student

###### **Latest degree**

Medical doctor

###### **Other areas of specialty/work**

General Practitioner

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Doctor Majid Rostami Moghaddam

**Position**

Dermatologist

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Romina Behboudi

**Position**

Medical Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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**Email**

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## 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