

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of anti-inflammatory effects of ZAX.1400.EC.02 drug on skin inflammation in patients with eczema

Protocol summary

Study aim

Determination of the anti-inflammatory effect of ZAX.1400.EC.02 on the course of the disease and symptomatic treatment of eczema

Design

In the double-blind clinical trial, two treatment, and control groups in parallel, 60 patients in the drug group and 50 patients in the control group, for randomization we will use the permutation block method with a number of 6 blocks using Random allocation software.

Settings and conduct

Patients with eczema referred to partner medical centers are divided into two groups A and B. The anti-inflammatory effects of ZAX.1400.EC.02 will be evaluated. Study at the level of the physician, clinical caregiver, patient and statistical analyst will be blind. Location: Fasa University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Diagnosis of the disease by a physician 2. Both sexes (male and female) 3. Having informed and written consent to participate in the study
Conditions for not entering the study: 1. The disagreement of the physician directly responsible for the patient 2. Allergy to food and health 3. Pregnancy and lactation 4. Blisters and infection caused by the disease

Intervention groups

Dividing patients into two similar groups A and B. While receiving written consent, the treatment group in addition to the standard ointment containing ZAX.1400.EC.02 and the control group uses only the standard drug.

Main outcome variables

VAS (Visual analogue Scale)

General information

Reason for update

Acronym

SFE

IRCT registration information

IRCT registration number: **IRCT20210218050404N3**

Registration date: **2022-02-14, 1400/11/25**

Registration timing: **prospective**

Last update: **2022-02-14, 1400/11/25**

Update count: **0**

Registration date

2022-02-14, 1400/11/25

Registrant information

Name

Amin Dakhili Ardestani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5335 9507

Email address

a.dakhili@fums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-05, 1400/12/14

Expected recruitment end date

2022-04-13, 1401/01/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of anti-inflammatory effects of ZAX.1400.EC.02 drug on skin inflammation in patients with eczema

Public title

Therapeutic effects of herbs on eczema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of the disease by a doctor Both sexes (male and female) Having informed and written consent to participate in the study

Exclusion criteria:

Pregnancy and lactation Food and health allergies بروز
تاؤل و عفونت ناشی از بیماری Disagreement of the physician directly responsible for the patient

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is performed on patients with eczema referred to the partner medical centers in the project. The relevant expert divides the patients into two similar groups based on the treatment regimen, age group, sex, severity of the disease and symptoms, and randomly, using the patient code numbers, one group is group A (herbal medicine) and one group is group B (standard medicine). For randomization, the permutation block method with the number of six blocks is done using Random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind the study, after the patient enters the study, the doctor prescribes A (drug) or B (placebo) based on the randomized form. The doctor's prescription is prescribed in the same packages. Clinical caregivers are unaware of the coding assigned to each patient. The person in charge of drug delivery and the patient, the doctor, the person in charge of evaluating the consequences will not know about the codings. The results of the two groups under the headings of groups A and B will be submitted to the statistical analyst.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Fasa University of Medical Sciences

Street address

Ibn Sina square, Fasa.

City

Fasa

Province

Fars

Postal code

7461686688

Approval date

2022-01-05, 1400/10/15

Ethics committee reference number

IR.FUMS.REC.1400.124

Health conditions studied

1

Description of health condition studied

Eczema

ICD-10 code

L23.9

ICD-10 code description

Allergic contact dermatitis, unspecified cause

Primary outcomes

1

Description

Extent of lesion

Timepoint

In seven turns; Days zero, 7, 14, 21, 28, 35 and 42

Method of measurement

Determine the area in CM2

2

Description

Redness of the skin

Timepoint

In seven turns; Days zero, 7, 14, 21, 28, 35 and 42

Method of measurement

Visual Analogue Scale checklist

3

Description

Swelling of the skin

Timepoint

In seven turns; Days zero, 7, 14, 21, 28, 35 and 42

Method of measurement

Visual Analogue Scale checklist

4

Description

Scaling

Timepoint

In seven turns; Days zero, 7, 14, 21, 28, 35 and 42

Method of measurement

Visual Analogue Scale checklist

5

Description

Itching

Timepoint

In seven turns; Days zero, 7, 14, 21, 28, 35 and 42

Method of measurement

Visual Analogue Scale checklist

6

Description

skin dryness

Timepoint

In seven turns; Days zero, 7, 14, 21, 28, 35 and 42

Method of measurement

VAS checklist

7

Description

Skin irritation

Timepoint

In seven turns; Days zero, 7, 14, 21, 28, 35 and 42

Method of measurement

Visual Analogue Scale checklist

8

Description

Skin scratches

Timepoint

In seven turns; Days zero, 7, 14, 21, 28, 35 and 42

Method of measurement

Visual Analogue Scale checklist

9

Description

Skin scars

Timepoint

In seven turns; Days zero, 7, 14, 21, 28, 35 and 42

Method of measurement

Visual Analogue Scale checklist

10

Description

Skin thickness

Timepoint

In seven turns; Days zero, 7, 14, 21, 28, 35 and 42

Method of measurement

Visual Analogue Scale checklist

11

Description

Skin rash

Timepoint

In seven turns; Days zero, 7, 14, 21, 28, 35 and 42

Method of measurement

Visual Analogue Scale checklist

12

Description

Recovery time

Timepoint

daily

Method of measurement

By day by checklist

Secondary outcomes

1

Description

Quality of Life

Timepoint

In seven turns; Days zero, 7, 14, 21, 28, 35 and 42

Method of measurement

DLQI form

Intervention groups

1

Description

Intervention group: ZAX.1400.EC.02 drug composition, topical and cream-based, twice-daily use for 21 days, and patients are evaluated for up to 42 days.

Category

Treatment - Drugs

2

Description

Control group: Betamethasone is used topically, twice daily, for 21 days, and patients are evaluated for up to 42 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamza Clinic

Full name of responsible person

Dr. Seyyed Amin Kouhpayeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

Fasa 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
Fasa University of Medical Sciences
Full name of responsible person
Amin Dakhili Ardestani
Position
کارشناس

Latest degree
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Person responsible for updating data

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amindakhiliardestani@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Some of the information obtained will be available based on changes in initial outcomes

When the data will become available and for how long

Start of access period 6 months after production of results

To whom data/document is available

People engaged in research in medical universities of the country

Under which criteria data/document could be used

The methods and data contained in this clinical trial should be used solely to advance similar projects. It is also necessary to mention the research center of this study (Fasa University of Medical Sciences) if the information is used

From where data/document is obtainable

Amin Dakhili Ardestani, Email Address:

Amindakhiliardestani@yahoo.com Contact Number:

09228584505 Address: Fasa University, Ibn Sina Square,

Fasa University of Medical Sciences and Health Services

What processes are involved for a request to access data/document

1. Contacting the general respondent of study 2. Sending his formal request to the respondent 3. The application form in the University Research Council 4. In case of a positive response from the council, it will be provided to the applicant in accordance with the ethical principles. 5. The total duration of the process is 20 days.

Comments