

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Therapeutic effects of ZAX.1400.P03 on cutaneous clinical manifestations in patients with psoriasis in Fasa city in 1400

Protocol summary

Study aim

Determination of therapeutic effects of cream containing ZAX.1400.P03 on skin inflammation caused by psoriasis

Design

The double-blindatment, and control groups in parallel, 52 patients in the drug group and 52 patients in the placebo group, for randomization we will use the permutation block method with several 6 blocks using Random allocation software.

Settings and conduct

Patients with psoriasis referred to partner medical centers are divided into two groups A and B. The anti-inflammatory effects of ZAX.1400.P03 will be evaluated. Study at the level of physician, outcome assessor, 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 doctor 2. Age range between 18 to 60 years 3. Both sexes (male and female) 4. Having informed and written consent to participate in study 5. Only local tissue involvement and no need to use Oral medications Conditions not included in the study: 1. Food and health allergies 2. Presence of underlying diseases and immunodeficiency 3. Pregnancy and lactation 4. Blisters and infections caused by the disease 5. Lack of consent of the physician directly responsible for the patient

Intervention groups

Dividing patients into two similar groups A and B. While receiving written consent, the treatment group in addition to the standard cream containing ZAX.1400.P03 and the control group in addition to the standard drug also uses a placebo.

Main outcome variables

VAS (Visual analogue Scale)

General information

Reason for update

Acronym

SFP

IRCT registration information

IRCT registration number: **IRCT20210218050404N5**

Registration date: **2022-03-03, 1400/12/12**

Registration timing: **prospective**

Last update: **2022-03-03, 1400/12/12**

Update count: **0**

Registration date

2022-03-03, 1400/12/12

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

2022-05-04, 1401/02/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effects of ZAX.1400.P03 on cutaneous clinical manifestations in patients with psoriasis in Fasa

city in 1400	
Public title	Therapeutic effects of herbs on psoriasis
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Diagnosis of the disease by a doctor Age range between 18 and 60 years Having informed and written consent to participate in the study Tissue involvement only locally and no need to take oral medications
Exclusion criteria:	Food and health allergies Existence of underlying diseases and immunodeficiency Incidence of blisters and infections caused by the disease Disagreement of the physician directly responsible for the patient Pregnancy and lactation
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: 104
Randomization (investigator's opinion)	Randomized
Randomization description	This study is performed on patients with psoriasis 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. B (placebo). 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.1400.125

Health conditions studied

1

Description of health condition studied

Psoriasis

ICD-10 code

L40.0

ICD-10 code description

psoriasis vulgaris

Primary outcomes

1

Description

Extent of lesion

Timepoint

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

Method of measurement

Relative determination of area with checkered paper

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

Visual Analogue Scale 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

pain

Timepoint

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

Method of measurement

Visual Analogue Scale checklist

9

Description

Skin scratches

Timepoint

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

Method of measurement

Visual Analogue Scale checklist

10

Description

Skin scars

Timepoint

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

Method of measurement

Visual Analogue Scale checklist

11

Description

Skin thickness

Timepoint

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

Method of measurement

Visual Analogue Scale checklist

12

Description

Skin rash

Timepoint

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

Method of measurement

Visual Analogue Scale checklist

13

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.P03 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: The placebo composition, colored with food coloring, is used topically, used twice a day, for a period of 21 days, and patients are evaluated for up to 42 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamza Clinic

Full name of responsible person

Dr. Seyyed Amin Kouhpayeh

Street address

Ibn Sina square, Fasa

City

Fasa

Province

Fars

Postal code

4737774617

Phone

+98 71 5335 9507

Email

kouhpayeha@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Dr. Yaser Mansouri

Street address

Ibn Sina square, Fasa

City

Fasa

Province

Fars

Postal code

7461686688

Phone

+98 917 132 5240

Email

FUMS.mansoori@gmail.com

Web page address

<https://www.fums.ac.ir>

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

Expert

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

Street address

Ibn Sina square, Fasa

City

Fasa

Province

Fars

Postal code

7461686688

Phone

0715335907

Email

amindakhiliardestani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Dr Seyyed Amin Kouhpayeh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Ibn Sina Square, Fasa.

City

Fasa

Province

Fars

Postal code

7461686688

Phone

+98 71 5335 9507

Email

kouhpayeha@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Amin Dakhili Ardestani

Position
Expert
Latest degree
Bachelor
Other areas of specialty/work
Anesthesiology
Street address
Ibn Sina Square, Fasa.
City
Fasa
Province
Fars
Postal code
7461686688
Phone
07 53359507
Email
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

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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