Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Formulation and clinical evaluation of hydrogel containing bisabolol nanocapsules for treatment of dermatitis

Protocol summary

Study aim
To assess the topical effect of gel containing bisabolol nanocapsules on the treatment of chronic eczema of the hand

Design
This is a double-blind randomized clinical trial, phase II, in which 70 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
Setting and conduct: The eligible patients with chronic eczema of the hand who will refer to Sina Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded so that the shape of the two types of gel will be similar and patients will not be aware of the type of cream they use. In addition, the assignment of the patients to the intervention and control groups will be done by a third person, therefore, the physician who will examine the patients will be aware of the intervention

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 12 to 65 years; Chronic eczema of the hand Exclusion criteria: Pregnancy or breastfeeding; Other concurrent skin lesions such as psoriasis; Immunodeficiency

Intervention groups
Intervention group: Topical Fluocinolone cream 25% (Manufactured by Behvarzan Pharmaceutical Company) plus topical gel containing bisabolol nanocapsules (Manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) for 2 weeks and then topical gel containing bisabolol nanocapsules alone for 4 weeks Control group: Topical Fluocinolone cream 25% (Manufactured by Behvarzan Pharmaceutical Company) plus topical placebo gel (Manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) for 2 weeks and then topical placebo gel alone for 4 weeks

Main outcome variables
Primary outcome: The severity of pruritus, The severity of skin lesions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200115046143N2**
Registration date: **2021-06-25, 1400/04/04**
Registration timing: **prospective**

Last update: **2021-06-25, 1400/04/04**
Update count: **0**

Registration date
2021-06-25, 1400/04/04

Registrant information

Name
Seyed Yaser Vafaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3426 6353

Email address
y.vafaei@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-23, 1400/09/02

Expected recruitment end date
2023-02-21, 1401/12/02

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation and clinical evaluation of hydrogel containing bisabolol nanocapsules for treatment of dermatitis

Public title

Formulation and clinical evaluation of hydrogel containing bisabolol nanocapsules for treatment of dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic eczema of the hand

Exclusion criteria:

Pregnancy or breastfeeding Other concurrent skin lesions such as psoriasis Immunodeficiency

Age

From **12 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications will be perfectly the same in the two groups. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double-blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2021-06-12, 1400/03/22

Ethics committee reference number

IR.UMSHA.REC.1400.225

Health conditions studied

1

Description of health condition studied

Eczema

ICD-10 code

L20.84

ICD-10 code description

Intrinsic (allergic) eczema

Primary outcomes

1

Description

The severity of pruritus

Timepoint

Before the intervention and 2 and 6 weeks after the intervention

Method of measurement

By taking history

2

Description

The severity of skin lesions

Timepoint

Before the intervention and 2 and 6 weeks after the intervention

Method of measurement

By clinical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Topical Flucinolone cream 0.25% (Manufactured by Behvarzan Pharmaceutical Company) plus topical gel containing bisabolol nanocapsules (Manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) for 2 weeks and then topical gel containing bisabolol nanocapsules alone for 4 weeks
Category
Treatment - Drugs

2

Description
Control group: Topical Flucinolone cream 0.25% (Manufactured by Behvarzan Pharmaceutical Company) plus topical placebo gel (Manufactured by the laboratory of School of Pharmacy, Hamadan University of Medical Sciences) for 2 weeks and then topical placebo gel alone for 4 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital in Hamadan City
Full name of responsible person
Homa Karami
Street address
Sina Hospital, Mirzadeh Eshghi Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3827 4184
Email
homa1karami@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
info.research@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Homa Karami
Position
Student of pharmacy
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0572
Email
homa1karami@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person

Dr Seyed Yaser Vafaei

Position
Assistant professor of pharmaceutics

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0572

Email
y.vafaei@umsha.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Ḍr Seyed Yase Vafaei

Position
Assistant professor of pharmaceutics

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0572

Email
y.vafaei@umsha.ac.ir

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