

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of a oil Containing Chamomile in the Treatment of Mild to Moderate Atopic Dermatitis: A Randomized, Double-blind controlled Trial

Protocol summary

Study aim

The effect of topical use of chamomile oil on the improvement of mild to moderate atopic dermatitis in infants. Determining and comparing SCORAD criteria as a measure of severity of the disease and reducing the amount of redness and dryness and the degree of itching and restlessness in the studied groups. Comprehensive and effective treatment for reducing and improving symptoms associated with atopic dermatitis in infancy

Design

Samples were assigned to randomly assigned block randomized sequences in two intervention groups (chamomile oil) and control group (oceerin). In a double blind randomized clinical trial 52 infants suffering from atopic dermatitis and eczema who referred to the clinic of Hashamateyeh Sabzevar Hospital. And have entry criteria and no exit criteria are included in the study by a pediatrician.

Settings and conduct

The site of the study is in the clinic of Hashamateyeh Sabzevar Hospital. On the first day of treatment, first, the areas affected by atopic dermatitis are washed with water and used on the wet skin of the mother-in-law. This is repeated twice a day and for 14 days for topical oil of Chamomile and Oceerin. In order to double the study, Oceerin was prepared in similar packages of the same shape and randomly assigned to each of the packages.

Participants/Inclusion and exclusion criteria

Conditions of entry: Infants with mild to moderate atopic dermatitis (based on SCORAD criteria and pediatrician diagnosis) and conditions of non-entry: There are skin lesions other than dermatitis

Intervention groups

Groups: chamomile oil topically twice a day for 14 days in the affected areas of atopic dermatitis in the control group with the same method oceerin is given.

Main outcome variables

Reducing the extent of skin involvement in the area of dermatitis; Reducing dryness and irritation and redness;

Reducing itching and insomnia and restlessness of infants;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180108038274N1**

Registration date: **2018-04-19, 1397/01/30**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-19, 1397/01/30**

Update count: **0**

Registration date

2018-04-19, 1397/01/30

Registrant information

Name

neda sirghani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

nedasirghani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-20, 1396/12/29

Expected recruitment end date

2018-08-22, 1397/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of a oil Containing Chamomile in the Treatment of Mild to Moderate Atopic Dermatitis: A Randomized, Double-blind controlled Trial

Public title

Efficacy of a oil Containing Chamomile in the Treatment Atopic Dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Infants with atopic dermatitis (based on SCORAD criteria and pediatrician diagnosis) Good birth weight for age Lack of underlying diseases and congenital disorders. Inclination mother's cooperation With the plan

Exclusion criteria:

Major medical diseases (immunodeficiency, growth and development disorders, genetic disorders) The presence of skin lesions other than eczema in the areas of topical application of the drug Use of medications that affect eczema during maternal or infant use Cancellation of the patient to continue the study

Age

To **1 year** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: The samples were randomly assigned sequences of quadrilateral blocks determined by the statistic consultant and the patients admitted to the clinic, respectively, in the two groups of intervention (local chamomile oil) and the control group (oserin). In A double-blind study that can distract the test result is hidden from both the patient and the researcher's point of view in clinical and therapeutic work. In most cases, double-blind testing is performed to achieve a higher scientific standard.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to double the study, oil was prepared in similar packages of the same shape and randomly assigned to each of the packages.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Sabzevar University of Medical Sciences and Health Services

Street address

University of Sabzevar, University of Tabriz, Sabzevar University of Medical Sciences and Health Services

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Approval date

2018-02-18, 1396/11/29

Ethics committee reference number

IR.MEDSAB.REC.1396.143

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

Atopic dermatitis

ICD-10 code

L20.9

ICD-10 code description

Atopic dermatitis, unspecified

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

The severity of the involvement of dermatitis

Timepoint

Before starting treatment and on days 6, 13, 27

Method of measurement

Questionnaire and with SCORAD criteria for atopic dermatitis

2**Description**

The dryness, redness and irritation

Timepoint

Before starting treatment and on days 6, 13, 27

Method of measurement

Questionnaire

3

Description

pruritus rate

Timepoint

Before starting treatment and on days 6, 13, 27

Method of measurement

Questionnaire

4

Description

Insomnia and restlessness of infants

Timepoint

Before starting treatment and on days 6, 13, 27

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Quality of Life

Timepoint

Before starting treatment and days 6, 13 and 27

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: Chamomile oil twice a day for 14 days

Category

Treatment - Drugs

2

Description

Control group: Oceerin twice a day for 14 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Heshmatieh Sabzevar specialized and specialized hospital

Full name of responsible person

Dr. Aqiyyullah Kikhosrowi

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshteh Gharat

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University of Blvd., Sabzevar University of Medical Sciences and Health Services, Department of Research and Technology

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drghorat@gmail.com

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

Yes

Title of funding source

Sabzevar 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**

Sabzevar University of Medical Sciences

Full name of responsible person

Neda Sirghani

Position

General 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**

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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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