Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the efficacy of hydrocortisone ointment and flax seed oil on skin eczema of children: A clinical trial study

Protocol summary

Study aim
Determining the effectiveness of hydrocortisone ointment and flax seed oil on skin eczema of children

Design
A phase 2, randomized, double-blind, controlled trial with parallel groups enrolled 92 participants. Randomization was performed using a computer-generated allocation sequence.

Settings and conduct
This study compares the effect of linseed oil with hydrocortisone ointment for the treatment of eczema in children referred to educational hospitals affiliated to Jundishapur University of Medical Sciences, Ahvaz. For double blinding, patients and researchers are unaware of the type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age: Children between 2 and 24 months of age will be eligible to participate. Eczema Diagnosis: Children with a confirmed diagnosis of eczema will be considered for enrollment. A minimum duration of one week since the onset of current eczema symptoms is required. Underlying Medical Conditions: Children with well-controlled underlying medical conditions may be included in the study after a thorough evaluation by the research team. Exclusion Criteria: Linseed Oil Use: Children who have used linseed oil within the past week will be excluded from the study.

Intervention groups
Randomization and Group Allocation: Children will be randomly assigned to one of two groups: Intervention Group: This group will receive flaxseed oil following a standardized usage guide with dosages determined based on the participants' weight. Control Group: This group will receive hydrocortisone ointment according to standardized guidelines established by a physician's recommendations and approved instructions.

Main outcome variables
Skin dryness; Stretch marks; Flax seed oil; Hydrocortisone ointment; Skin healing

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240614062125N1**
Registration date: **2024-07-29, 1403/05/08**
Registration timing: **prospective**

Last update: **2024-07-29, 1403/05/08**
Update count: **0**

Registration date
2024-07-29, 1403/05/08

Registrant information

Name
Ashrafalsadat Hakim

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-08-15, 1403/05/25

Expected recruitment end date
2024-09-15, 1403/06/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of the efficacy of hydrocortisone ointment and flax seed oil on skin eczema of children: A clinical trial study

Public title
Treating Eczema in Children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children with eczema symptoms. Age of the child between 2 months and 24 months. No history of uncontrolled underlying disease. Parents have the ability to receive education (at least elementary literacy level). Parents have not participated in a previous class.
Exclusion criteria:
Children under 2 months and over 24 months
Age
From **2 months** old to **24 months** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **92**
Randomization (investigator's opinion)
Randomized
Randomization description
The research sample was first selected from the research community based on the inclusion criteria. Random assignment to the two test and control groups will be conducted using a blocked randomization technique with four permutation blocks (selected from a table of 24 possible blocks). This method ensures that the number of participants in each group is nearly equal. Blocks are formed based on relevant variables, and within each block, half are assigned to the test group and half to the control group. This approach aims to achieve balanced group sizes.
Blinding (investigator's opinion)
Double blinded
Blinding description
Double-blind Randomized Clinical Trial The study employs a double-blind randomized controlled trial (RCT) design to minimize bias and ensure the objectivity of the results. This means that neither the participants (children) nor the researchers administering the treatments know which group a participant belongs to. Randomization and Group Allocation Participants are randomly assigned to either the test group (flaxseed oil) or the control group (hydrocortisone ointment) using a randomization process. Treatment Preparation and Masking To maintain blinding, both the flaxseed oil and hydrocortisone ointment are prepared in identical containers and labeled with neutral codes (e.g., "H" for hydrocortisone, "T" for flaxseed oil) by an independent person not involved in the treatment assignment or data collection. Double-blinding Implementation The coded containers are then distributed to the participants according to their group assignment. Researchers who interact with the participants and collect data are also blinded to the treatment groups. This ensures that neither the participants' expectations nor the researchers' assessments are influenced by the knowledge of which treatment a participant is receiving.
Placebo
Not used
Assignment
Parallel
Other design features
This study will employ a randomized controlled trial (RCT) design. Participants will be recruited and randomly assigned to either the test group (N=46) or the control group (N=46) using a randomized permutation method. This ensures that any observed differences in treatment outcomes are more likely due to the intervention rather than pre-existing differences between the groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Working Group in University Research
Street address
Jundishapur University of Medical Sciences, Esfand Street, Golestan Blvd., Ahvaz
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Ahvaz
Province
Khouzestan
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6135715794
Approval date
2024-06-01, 1403/03/12
Ethics committee reference number
IR.AJUMS.REC.1403.110

Health conditions studied

1

Description of health condition studied
Eczema
ICD-10 code
L20.8
ICD-10 code description
Other atopic dermatitis

Primary outcomes

1

Description

Skin dryness

Timepoint

Baseline (before intervention) and weeks 1, 2, and 3 following the start of treatment with flaxseed oil or hydrocortisone ointment.

Method of measurement

Distance measurement: The distance from the "No dryness" end to the participant's mark is measured, often in millimeters.Higher scores = more dryness: A greater distance indicates a higher level of perceived skin dryness.

2

Description

Stretch marks

Timepoint

Baseline (before intervention) and weeks 1, 2, and 3 following the start of treatment with flaxseed oil or hydrocortisone ointment.

Method of measurement

Visual Analogue Scale : We could simply count the total number of stretch marks present in the affected area at each time point. The length and width of individual stretch marks could be measured to assess their size.

3

Description

Skin healing

Timepoint

Baseline (before intervention) and weeks 1, 2, and 3 following the start of treatment with flaxseed oil or hydrocortisone ointment.

Method of measurement

Visual Analogue Scale for Improvement: The Visual Analogue Scale could be adapted to capture the participant's perception of their skin healing progress. The scale could be labeled with descriptors like "No improvement" on one end and "Completely healed" on the other. Participants would mark the point that best reflects their current state of skin healing.

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group": Children in the test group will receive linseed oil according to dosage instructions and weight-based adjustments.

Category

Treatment - Drugs

2

Description

"Control group:" The control group uses hydrocortisone ointment. Also, the use of hydrocortisone ointment is done according to the doctor's recommendations and valid instructions for the control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital (RA)

Full name of responsible person

Ashrafalsadat Hakim

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mehrnoosh Zakirkish

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

AshrafalSadat Hakim

Position

Assistant professor, faculty member

Latest degree

Master

Other areas of specialty/work

Pediatrics

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Position

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Other areas of specialty/work

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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