Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of topical application of human breast milk and Hydrocortisone ointment 1% on healing of infantile atopic eczema

Protocol summary

Summary

Infantile atopic eczema is an inflammatory lesion that usually involves the epidermis of the skin and almost 50% of all children are affected in the first years of their life. Most of interventions and treatments have explored the effects of probiotics and synthetic drugs on atopic eczema and less attention has been to complementary, traditional and alternative medicines. The aim of current study was comparing topical application of human breast milk and Hydrocortisone ointment 1% on healing of infantile atopic eczema. A randomized controlled clinical trial on 104 healthy infants with age of less than 20 months without having major diseases that needed long term treatments referred to Amiri Kabir Hospital at Arak city in 2011-2012. The infants were randomly divided into two groups (with using a coin); topical application of human breast milk (N=54) and Hydrocortisone ointment 1% (N=50). Human breast milk group used hind milk after each breastfeeding and other group used Hydrocortisone ointment 1% two times daily. For assessment of extent and severity of eczema, we used objective SCORAD (SCORing Atopic Dermatitis) and PO SCORAD (Patient-Oriented SCORing Atopic Dermatitis) at days 0, 7, 14 and 21 in each group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208313869N5**
Registration date: **2013-03-01, 1391/12/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-03-01, 1391/12/11

Registrant information

Name
Leila Amirifarahani
Name of organization / entity
Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 86 1417 3524
Email address
l.amirifarahani@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2011-07-25, 1390/05/03

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of topical application of human breast milk and Hydrocortisone ointment 1% on healing of infantile atopic eczema

Public title

Effect of topical application of human breast milk on treatment of infants eczema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having less than 20 months and atopic eczema Exclusion criteria:having major diseases that needed long term treatments

Age
To **2 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **104**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Arak University of Medical Sciences
Street address
Arak University of Medical Sciences, Sardash, Arak
City
Arak
Postal code
Approval date
2011-07-04, 1390/04/13
Ethics committee reference number
90-109-5

Health conditions studied

1

Description of health condition studied
Infantile atopic dermatitis
ICD-10 code
L20
ICD-10 code description
Atopic dermatitis

Primary outcomes

1

Description
Extent of infantile atopic eczema
Timepoint
Before intervention and days 7, 14 and 21 after intervention
Method of measurement
Using objective SCORAD and PO SCORAD

Secondary outcomes

1

Description
Severity of infantile atopic eczema
Timepoint
Before intervention and days 7, 14 and 21 after intervention
Method of measurement
Using objective SCORAD and PO SCORAD

Intervention groups

1

Description
Intervention group used topical application of human breast milk (hind milk) after each breastfeeding
Category
Treatment - Other

2

Description
Control group used Hydrocortisone ointment 1% two times daily
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak University of Medical Sciences
Full name of responsible person
Leila Amiri Farahani
Street address
Arak University of Medical Sciences, Sardasht, Arak
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
Dr Saeed Changizi Ashtyani
Street address

Arak University of Medical Sciences, Sardash, Arak, University of Medical Sciences Vice chancellor for research, Dr Saeed Changizi Ashtyani

City

Arak

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Leila Amiri Farahani

Position

Member of faculty/MSc

Other areas of specialty/work

Street address

Arak University of Medical Sciences, Sardasht, Arak

City

Arak

Postal code

Phone

+98 86 1417 3524

Fax

Email

l.amirifarahani@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Leila Amiri Farahani

Position

Member of faculty/ MSc

Other areas of specialty/work

Street address

Arak University of Medical Sciences, Sardasht, Arak

City

Arak

Postal code

Phone

+98 86 1417 3524

Fax

Email

l.amirifarahani@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Leila Amiri Farahani

Position

Member of faculty/ MSc

Other areas of specialty/work

Street address

Arak University of Medical Sciences, Sardasht, Arak

City

Arak

Postal code

-

Phone

+98 86 1417 3524

Fax

+98 86 1417 3524

Email

l.amirifarahani@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty