

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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