

# 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**

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**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**

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**Position**

Member of faculty/MSc

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**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*