Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of topical application of breast human milk and Hydrocortisone 1% ointment on diaper dermatitis healing among infants

Protocol summary

Summary

A clinical trial on 140 infants (70 patients in each group) suffering from diaper dermatitis that referred to Amir Kabir hospital. This study compared the effect of breast feeding and use of topical hydrocortisone ointment 1% for healing diaper dermatitis in infants. Initially selected based on Form Action Research Unit eligible to be selected. Research Selection criteria included Infants under 24 months, there is no known diseases that require to special treatment, no using other drugs for healing diaper dermatitis, no using antibiotics during research, there is no fungal dermatitis by exploration of physician . Then infants randomly to 2 groups, taking topical applicaton of breast milk and hydrocortizone1% . Group control ointment hydro cortisone 1% rate of two times a day after washing and changing diaper at the site of dermatitis . diaper drmatitis will evaluate by six-point scale in days 0,3 and 7 in two groups . full healing time will calculate and compare in two groups .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102163869N2**
Registration date: **2011-06-03, 1390/03/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-06-03, 1390/03/13

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

2010-09-06, 1389/06/15

Expected recruitment end date

2011-02-04, 1389/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of topical application of breast human milk and Hydrocortisone 1% ointment on diaper dermatitis healing among infants

Public title

Comparison of topical application of breast human milk and Hydrocortisone 1% ointment on diaper dermatitis healing among infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Infants under 24 months, Exclusion criteria: there is known diseases that require to special treatment, using other drugs for healing diaper dermatitis, using antibiotics during research, there is fungal dermatitis by exploration of physician

Age

To **2 years** old

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **140**
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

1

Registry name
Arak University Of Medical Sciences
Secondary trial Id
89-86-8
Registration date
2010-06-30, 1389/04/09

Ethics committees

1

Ethics committee
Name of ethics committee
Arak University Of Medical Sciences
Street address
Arak University Of Medical Sciences, Sardasht, Arak
City
Arak
Postal code
Approval date
2010-06-30, 1389/04/09
Ethics committee reference number
89-86-8

Health conditions studied

1

Description of health condition studied
Diaper dermatitis
ICD-10 code
L22
ICD-10 code description
Diaper [napkin] dermatitis

Primary outcomes

1

Description
severity of diaper dermatitis
Timepoint
before teratment,days of 3 and 7 after treatment
Method of measurement
6-point scale for severity of diaper dermatitis

Secondary outcomes

1

Description
healing time for diaper dermatitis
Timepoint
healing time for diaper dermatitis
Method of measurement
6-point scale for severity of diaper dermatitis

Intervention groups

1

Description
group1: using topical application of hind milk after diaper change
Category
Treatment - Drugs

2

Description
group2: using topical application of Hydrocortizone 1%
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Kabir Hospital in Arak
Full name of responsible person
Street address
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University Of Medical Sciences
Full name of responsible person
Leila Amiri Farahani
Street address

Arak University Of Medical Sciences, Sardasht, Arak

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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 in midwifery group

Other areas of specialty/work

Street address

Arak University Of Medical Sciences, Sardasht, Arak

City

Arak

Postal code

Phone

+98 86141735025

Fax

Email

l.amirifarahani@arakmu.ac.ir

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

MSc of Midwifery

Other areas of specialty/work

Street address

Arak University Of Medical Sciences, Sardasht, Arak

City

Arak

Postal code

Phone

+98 86141735025

Fax

Email

l.amirifarahani@arakmu.ac.ir

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

MSc of midwifery

Other areas of specialty/work

Street address

City

Postal code

Phone

Fax

Email

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