

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of efficacy of traditional medication of Henna and Hydrocortisone ointment 1% on diaper dermatitis healing among infants

Protocol summary

Summary

The aim of this study was to compare the effectiveness of topical application of traditional medicine products "Henna", and %1 Hydrocortisone ointment on treatment level of diaper dermatitis in children under two years old. This study was a double blind randomized clinical trial. Eighty-eight infants under two years, referred to a hospital clinic with diaper dermatitis were selected and divided randomly into two groups. Then the mothers were instructed to put the ointment on the affected area three times daily after cleaning and washing there. The severity and extension of dermatitis areas was measured at first, third and the fifth day after intervention and the rate of recovery were compared in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080318665N1**

Registration date: **2014-09-23, 1393/07/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-09-23, 1393/07/01

Registrant information

Name

Abdollah Keshavarz

Name of organization / entity

Research Institute for Islamic and Complementary Medicine ; Iran University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 3366 4302

Email address

salamatparsi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Iran University Of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of traditional medication of Henna and Hydrocortisone ointment 1% on diaper dermatitis healing among infants

Public title

Comparison the effect of traditional medication of Henna and Hydrocortisone ointment 1% on diaper dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The Infants under 24 months. Exclusion criteria: Existence of known diseases that need special treatment; The use of other drugs for healing diaper dermatitis; The use of antibiotics during research; Existence diaper dermatitis due to fungal that diagnosed by Pediatrician

Age

From **1 month** old to **2 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 88

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Institute for Islamic and Complementary
Medicine ; Iran University Of Medical Sciences

Street address

No. 9, Pirnia Alley, North Laleh-Zar Street, Tehran,
Iran

City

Tehran

Postal code

-

Approval date

2012-12-16, 1391/09/26

Ethics committee reference number

11180/م/ت

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

The severity of dermatitis

Timepoint

Baseline, days 3 and 5 of study

Method of measurement

Six-point scale for severity of diaper dermatitis

Secondary outcomes

1

Description

Dermatitis extent- Side effects

Timepoint

Baseline, days 3 and 5 of study

Method of measurement

Checklist

Intervention groups

1

Description

Group 1: To use traditional product of henna three times
a day after diaper change.

Category

Treatment - Drugs

2

Description

Group 2: To use one percent hydrocortisone ointment
twice daily for the affected area.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods Children's Medical Center

Full name of responsible person

Dr. Keshavarz

Street address

Qods Square, Shahid Beheshti Blvd, Qazvin, Iran

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University Of Medical Sciences

Full name of responsible person

Ashkan Divanbeighi

Street address

Hemmat Highway, Iran University of Medical
Sciences, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

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Person responsible for general inquiries**Contact****Name of organization / entity**

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Other areas of specialty/work**Street 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