Comparison the effect of cream containing 2% magnesium versus Calendula cream on diaper rash

Protocol summary

Summary
Objectives: Determination of effect of topical application of magnesium 2% containing cream in the treatment of diaper rash. Design: Double blind, control with placebo, single center. Setting and Conduct: 64 diaper rash patients in Pediatric ward in Hajar Hospital in Shahrekord randomly assigned into two groups: experiment and control groups. Participants: Inclusion criteria are diagnosis of diaper rash; children under 2 years. Exclusion criteria: other diseases with diaper rash such as lupus. Intervention: Intervention group will be used Calendula cream combined with magnesium 2%. The control group will be used cream contain calandula for the same time with intervention group. Intervention period: Two weeks. Main outcome measures: diaper rash symptoms.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2012070910222N1
Registration date: 2012-12-17, 1391/09/27
Registration timing: retrospective

Registration date
2012-12-17, 1391/09/27

Registrant information
Name
Zahra Keivani
Name of organization / entity
Shahrekord University Of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 38 1222 0016
Email address
keivani@skums.ac.ir

Recruitment status
Recruitment complete

Funding source
Vice Chancellor for Research, Shahrekord Univrsity of Medical Sciences

Expected recruitment start date
2012-09-20, 1391/06/30
Expected recruitment end date
2012-10-21, 1391/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of cream containing 2% magnesium versus Calendula cream on diaper rash

Public title
Effect of topical application of magnesium 2% containing Cream in the treatment of diaper rash

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: diagnosis of diaper rash; children under 2 years. Exclusion Criteria: other diseases with diaper rash such as lupus.

Age
To 2 years old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: 64

Randomization (investigator’s opinion)
Randomized

Randomization description
Double blinded

Blinding (investigator’s opinion)

Blinding description

Placebo
Used
**Secondary Ids**
empty

**Ethics committees**

1

**Ethics committee**

Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences

Street address
Ethics Committee, Shahrekord University of Medical Sciences, Kashani Street

City
Shahrekord

Postal code
Approval date
2012-07-19, 1391/04/29

Ethics committee reference number
91-4-8

**Health conditions studied**

1

**Description of health condition studied**
diaper rash

ICD-10 code
L22

ICD-10 code description
Diaper [napkin] dermatitis

**Primary outcomes**

1

**Description**
diaper rash symptoms

Timepoint
at base line, two weeks later

Method of measurement
Observation

**Secondary outcomes**

1

**Description**

Timepoint

Method of measurement

**Intervention groups**

1

**Description**
Control group: 2 weeks; cream contain calandula

Category
Placebo

2

**Description**
Intervention group: 2 weeks; Calendula cream combined with magnesium2%

Category
Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

Name of recruitment center
Hajar Hospital Shahrekord

Full name of responsible person
Zahra Keivani

Street address
Department of Research, Shahrekord University of Medical Sciences

City
Shahrekord

**Sponsors / Funding sources**

1

**Sponsor**

Name of organization / entity
Vice chancellor for research, Shahrekord University of Medical Sciences

Full name of responsible person
Vice chancellor for research, Shahrekord University of Medical Sciences

Street address
Vice chancellor for research, Shahrekord University of Medical sciences

City
Shahrekord

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, Shahrekord 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
Shahrekord University Of Medical Science
Full name of responsible person
Zahra Keivani
Position
Master of Nursing
Other areas of specialty/work
Street address
Shahrekord, Shahrekord University Of Medical Science
City
Shahrekord
Postal code
Phone
+98 38 1222 0016
Fax
Email
keivaniz@yahoo.com
Web page address

Person responsible for scientific inquiries
Contact
Name of organization / entity
Shahrekord University Of Medical Science
Full name of responsible person
Dr. Mohammad Kazem Nourbakhsh
Position
Assistant Professor
Other areas of specialty/work
Street address
Shahrekord University Of Medical Science
City
Shahrekord
Postal code
Phone
+98 38 1222 0016
Fax
Email
keivaniz@yahoo.com
Web page address

Person responsible for updating data
Contact
Name of organization / entity
Shahrekord University Of Medical Science
Full name of responsible person
Zahra Keivani
Position
Master of Nursing
Other areas of specialty/work
Street address
Shahrekord, Shahrekord University Of Medical Science
City
Shahrekord
Postal code
Phone
+98 38 1222 0016
Fax
Email
keivaniz@yahoo.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