Clinical Trial Protocol
Iranian Registry of Clinical Trials
01 Mar 2020

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 of age. 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 calendula 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

Last update: 0
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

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 of age. 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

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used
Assignment
Parallel

Other design features

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**
Shahrekord University Of Medical Science

**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**
  Shahrekord,Shahrekord University Of Medical Science
- **Street address**
  Shahrekord,Shahrekord University Of Medical Science
- **City**
  Shahrekord
- **Postal code**
  00
- **Phone**
  +98 38 1222 0016
- **Fax**
  keivaniz@yahoo.com
- **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**
  Shahrekord University Of Medical Science
- **Street address**
  Shahrekord,Shahrekord University Of Medical Science
- **City**
  Shahrekord
- **Postal code**
  00
- **Phone**
  +98 38 1222 0016
- **Fax**
  keivaniz@yahoo.com
- **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**
  Shahrekord,Shahrekord University Of Medical Science
- **Street address**
  Shahrekord,Shahrekord University Of Medical Science
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- **Fax**
  keivaniz@yahoo.com
- **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