

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

A comparative trial of three medicines including: Nystatin, Cloterimazole and Mupirocine to treat a diaper dermatitis.

Protocol summary

Summary

A randomized clinical trial among children under 2 years with complaint of diaper dermatitis who has been visited as out patients in bandar abbas children hospital who has inclusion criteria for enrolment in this study.

Diagnostic criteria . macule , papule, plaque, vesicle, desquamation, maceration over inner side of thigh or buttock also lower part of abdomen. To determine severity, each of skin lesion received one point and according to the scores divided patients in three category: mild with score of 1, moderate with score of 2 and severe with score of 3 and more 164 Patients with maximum age of 2 years old who has been admitted in out patient department of Bandar Abbas Children's Hospital with complaint of Diaper Dermatitis randomly would be divided by random digit table into 4 groups (41 patients in each group) and Respectively would receive Clotrimazole (twice daily), Mupirocin (4 times a day), Nystatin (three times a day) or zinc oxide (4 times a day) plus Hydrocortison (3 times a day) for one week and they would be visited by their doctor's. According to response to treatment they would be divided in three groups with the same scale we used to determine severity of dermatitis. Complete relief (score zero) , partially treated (score 1-2), no response (score 3 and more)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112215458N1**
Registration date: **2015-03-26, 1394/01/06**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-03-26, 1394/01/06

Registrant information

Name

Rakhshane Goodarzi

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 76 1666 6242

Email address

rgoodarzi@oldhums.ac.ir

Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative trial of three medicines including: Nystatin, Cloterimazole and Mupirocine to treat a diaper dermatitis.

Public title

Survey the effects of antifungal medicines for treatment of napkin dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1. Age 0-2 years 2. minimum severity

score 1 3 duration less than 6 weeks Exclusion Criteria:
1.Duration of disease more than 6 weeks 2. Another
Perineal diseases like Psoriasis, Perineal infection ,
Perineal or genital wart, contact allergic dermatiti 3.
congenital immunodeficiency diseases 4.Previous
Treatment with
clotrimazole,Nystatin,Mupirocine,hydrocortison except
zinc oxide within 2 weeks before enrollment 5.Allergy to
Clotrimazol, Nystatin, Zinc
oxide,Mupirocine,hyrdocortison 6.treatment with
systemic corticosteroid,Antifungal or Antibiotic during
study

Age

To 2 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 164

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

HEC

Street address

Homozgan University of Medical Sciences

City

Bandar Abbas

Postal code**Approval date**

2013-08-12, 1392/05/21

Ethics committee reference number

HEC-92-5-21-1

Health conditions studied**1****Description of health condition studied**

Diaper(Napkin) Dermatitis

ICD-10 code

L22

ICD-10 code description

Diaper or Napkin: erythema rash

Primary outcomes**1****Description**

sevierty of dermatitis To determine severity, each of skin
lesion received one point and according to the scores
divided patients in three category: mild with score of 1,
moderate with score of 2 and severe with score of 3 and
more

Timepoint

baseline and one week after study

Method of measurement

According to response to treatment they would be
divided in three groups with the same scale we used to
determine severity of dermatitis. Complete relief (score
zero) ,partially treated (score 1-2), no response (score 3
and more)

Secondary outcomes**1****Description**

medication side effect, extension of dermatitis

Timepoint

baseline and 1 week after study

Method of measurement

Checklist

Intervention groups**1****Description**

Control Group: Zinc Oxide Cream four times a day plus
Hydrocortison Cream three times a day for one week .
1FTU(one Finger Tube Unite equal to Distal phalanx of
index finger)for an area of skin on a child equivalent to
twice the size of the palmar

Category

Treatment - Drugs

2**Description**

Intervention Group 1: Clotrimazol Cream two times daily
plus Hydrocortisone Cream Three times a day for one
week . 1FTU(one Finger Tube Unite equal to Distal
phalanx of index finger)for an area of skin on a child
equivalent to twice the size of the palmar

Category

Treatment - Drugs

3**Description**

Intervention Group 2: Nystatin Cream two times daily plus Hydrocortisone Cream Three times a day for one week . 1FTU(one Finger Tube Unite equal to Distal phalanx of index finger)for an area of skin on a child equivalent to twice the size of the palmar

Category

Treatment - Drugs

4

Description

Intervention Group 3: Mupirocin Cream four times daily plus Hydrocortisone Cream Three times a day for one week . 1FTU(one Finger Tube Unite equal to Distal phalanx of index finger)for an area of skin on a child equivalent to twice the size of the palmar

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bandar Abbas Children's Hospital

Full name of responsible person

Dr.Rakhshane Goodarzi

Street address

City

BandarAabbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Dr.Rakhshane Goodarzi

Street address

Hormozgan University of Medical Sciences

City

Bandar Abbas

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hormozgan 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

Hormozgan Univesity of Medical sciences

Full name of responsible person

Dr.Mohammad Mehdi Houshmandi

Position

Pediatrics

Other areas of specialty/work

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Position

Neonatologist, Academic Staff

Other areas of specialty/work

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Position

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Other areas of specialty/work

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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