

# Effect of Topical Application of the Cream Containing Magnesium 2% on Treatment of Diaper Dermatitis and Diaper Rash in Children A Clinical Trial Study

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## ABSTRACT

**Introduction:** Diaper dermatitis is referred to the inflammation in outer layers of the skin in the perineal area, lower abdomen, and inner thighs. The lesions are maculopapular and usually itchy, which could cause bacterial or candida infection, and predispose the infants to penis or vaginal and urinary infection and lead to discomfort, irritability, and restlessness. The drugs which have been so far administered for this disease (topical steroids) cause special complications for the sensitive skin in this area. Magnesium (Mg) is known for its anti-inflammatory and wound-healing properties.

**Aim:** The aim of the present study was to study the effect of the cream containing Mg 2% on treatment of diaper dermatitis and diaper rash in children.

**Materials and Methods:** In this clinical trial study, 64 children aged less than two years old with diaper dermatitis referring Paediatric Ward of Hajar Hospital were randomly assigned to two groups of 32. Group one was treated with the combined cream Mg 2% and Calendula and group two with Calendula cream alone. The duration of recovery was compared between the two groups.

**Results:** The duration of recovery was significantly lower in the intervention group than the control group ( $p$ -value<0.001), but there was no significant difference in the lesions size and diapers' number between the two groups.

**Conclusion:** Based on the finding of this study, Mg is effective on treatment of diaper dermatitis and could be used for treating diaper dermatitis and other types of dermatitis.

**Keywords:** Calendula, Inflammation, Ointment

## INTRODUCTION

Dermatitis is a skin disease and dermatitis diaper is the most frequent type of contact dermatitis in children. This disease involves an area of skin in infants which is usually covered by a napkin or diaper. Although the reason for this disease is not exactly known, the factors including mechanical friction, moisture, urinary and fecal contact, and pH changes contribute to its incidence [1]. The disease frequency has been reported 7 to 35% and even up to 50% in different studies.

The children have been reported to suffer from diaper dermatitis in the USA, Japan, Italy, and Iran 75%, 87%, 15% [2], and 34.9% respectively. This disease usually starts within the age of the third and 12<sup>th</sup> weeks and the peak of its incidence is the age of 6-12 months [3].

This disorder could be a predisposing factor for bacterial and fungal infection because of causing wounds accompanied with scaling, itching, burning, dryness, scratching, skin rubbing, as well as stimulants and microbes penetration [4]. In addition, it causes restlessness, suboptimal breast feeding, and sleeplessness, which leads to repeated referring to paediatricians and increased concern and anxiety in parents [5]. Moreover, the repeated referring by parents imposes a large financial burden on them.

All these indicate that treatment of diaper dermatitis is very important. Currently, many treatments are available including topical use of Vaseline, zinc oxide [6], and vitamin A [7] and calendula [8].

In the case of fungal infections and symptoms exacerbations, topical anti-fungal drugs (such as clotrimazole, miconazole, and nystatin) [9] and corticosteroids [10] are used. Topical corticosteroids are common therapies of this disease, but long term consumption of them is associated with side effects such as epidermis atrophy, pituitary-adrenal axis suppression, Cushing's syndrome, growth interruption [11], and Granuloma gluteal infants [12].

Calendula is an ointment that is a known drug in Iran and all over the world. This drug is used in atopic dermatitis, relief of itching, and no remarkable side effect is reported yet [8].

Proksch et al., in a study carried out by bathing with dead sea salts, concluded that the hydration of the skin and reduction of its redness is resulted from magnesium in the salt sea [13]. Besides, in another study, Dendra and his colleagues examined the use of magnesium salt in the skin wound and concluded that the impact of the product depends on the method and type of its use [14].

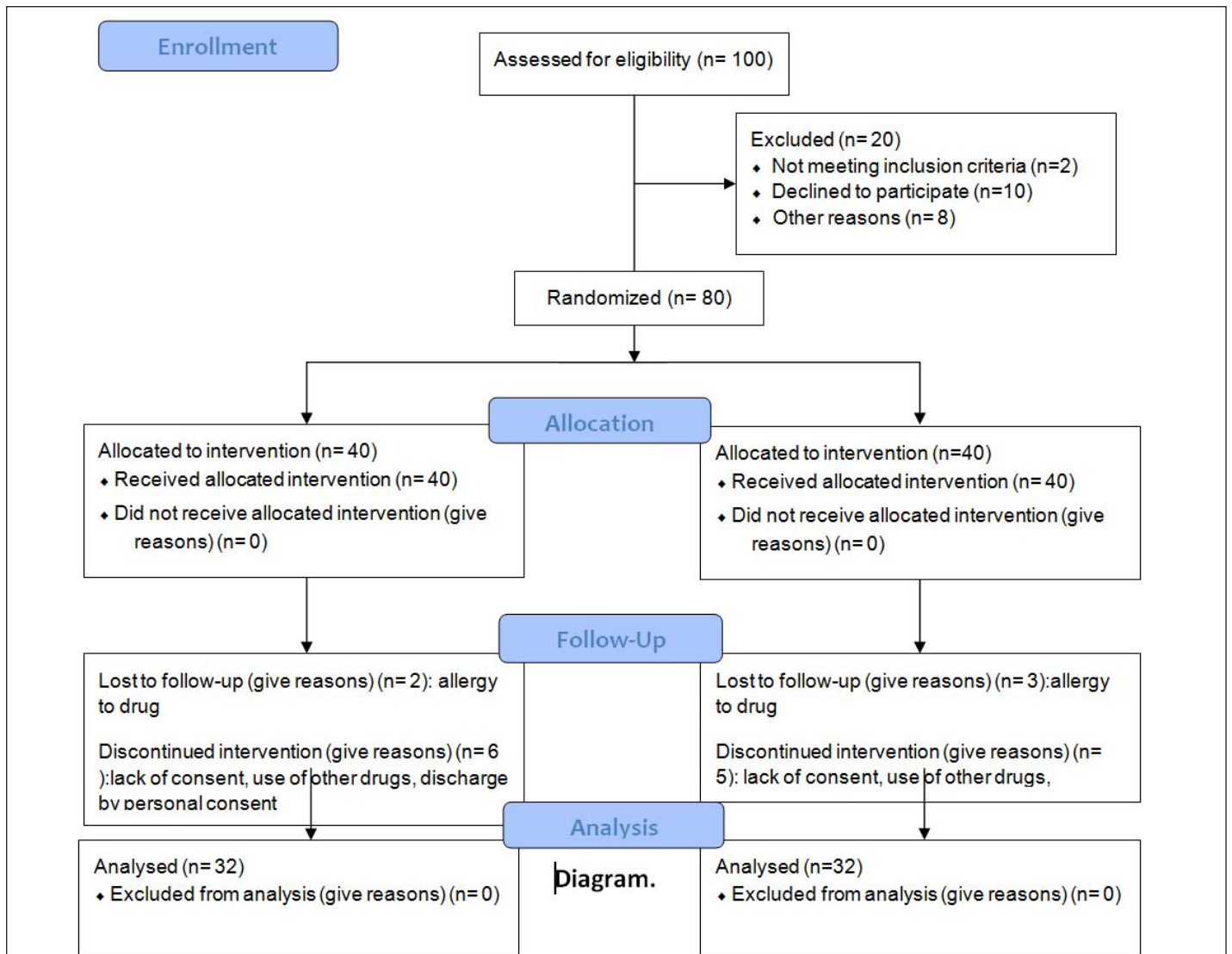
Regarding these complications and since magnesium (Mg) has been referred as anti-inflammatory, wound-restorative, and inflammation-declining in atopic dermatitis, therefore, we aimed to determine the efficacy of topical application of the cream containing Mg 2% on treatment of diaper dermatitis in children referring Paediatric Ward of Hajar Hospital, Shahrekord Iran.

## MATERIALS AND METHODS

In this double-blinded clinical trial study, the study population comprised 64 children [Table/Fig-1] less than two years old with diaper dermatitis admitting in Paediatric Ward of Hajar Hospital, Shahrekord. The inclusion criteria were patients aged less than two years with diaper dermatitis diagnosis and the exclusion criteria were co-morbidities like candida infection in groin, psoriasis, zinc deficiency, and use of other drugs for diaper dermatitis. Random Sampling was done lasting for six months. Groups were assigned through selecting one from every pair. The patients were examined once a day for the first five consecutive days of the study.

The sampling was done randomly and 32 children were included in each group. As far as we searched, no reliable criterion was found to determine lesion severity and therefore duration of recovery was used.

The patients underwent treatment with combined calendula and Mg 2% cream in case group and with calendula cream in control group.



[Table/Fig-1]: CONSORT 2010 Flow Diagram

The drugs used in this study included magnesium USP (Merck, Germany) and Calendula ointment (Dineh, Iran). The cream was used three times a day on the rash area while diaper changing. The follow-up was done twice a day until complete recovery. Furthermore, the drug administration continued until complete recovery, that is, removal of inflammation, redness, and lesions. Finally, the patient's recovery was determined based on the duration. The data were analysed by SPSS 16 using t-test and chi-square.

		Perineal	Genital	Groin	Total
Lesion site	Case group	65.6%	15.6%	18.8%	100%
	Control group	56.2%	3.1%	40.6%	100%
	Aggregate	60.9%	9.4%	29.7%	100%
$\chi^2 = 5.47 \quad p = 0.065$					

[Table/Fig-2]: Lesion site.

		Mean	Standard deviation	p-value	t value	Confidence interval	
						Lower limit	Upper limit
Age (year)	Case group	1.9375	0.84003	0.625	0.491	-0.28755	0.47505
	Control group	1.8438	0.67725				
Recovery duration (day)	Control group	3.25	0.67	0.00	1.102	0.788	2.726
	Case group	1.50	0.50				

[Table/Fig-3]: Age and recovery duration in case and control groups.

This research project was approved at Ethics Committee of Shahrekord University of Medical Sciences (ethical code: 8-4-91) and registered as IRCT2012110510222N2 in Iranian Registry of Clinical Trials (IRCT). Informed consent was obtained from all infants' parents.

## RESULTS

In this study, 64 children aged less than two years were entered. Mean age was  $1.9 \pm 0.8$  years in the case group and  $1.9 \pm 0.6$  years in the control group there is no significant difference between means ( $p$ -value=0.6). The two groups were matched by lesion site and there was no significant difference in this regard) (0.065) [Table/Fig-2]. In the case group, 18.8% of the patients had history of dermatitis and in the control group, 4.9% of infants that there was no significant difference between the two groups ( $p$ -value =0.2) in this respect. Mean duration of recovery was  $1.5 \pm 0.5$  days in the case group and  $3.25 \pm 0.67$  days in the control group. The mean duration of recovery was significantly lower in the case group than the control group [Table/Fig-3].

## DISCUSSION

The present study aimed to determine the efficacy of topical application of the cream containing Mg 2% on treatment of diaper dermatitis. In this study, 64 children less than two years were studied. According to the findings of this study, the mean duration of recovery was  $1.5 \pm 0.5$  days in the case group and  $3.25 \pm 0.67$  days in the control group. The mean duration of recovery was significantly lower in the case group than the control group ( $p$ -value <0.001).

In James et al., study, the effect of Mg-aluminum hydroxide stearate on eczema dermatitis was investigated and the contribution of topical cream to protection from the skin against allergens and external stimulants was indicated. The notable point was that skin restoration was mainly through moisture and skin lipid replacement and hence the symptoms of dermatitis decreased.

This cream relieves irritation and itching in different types of dermatitis including atopic, contact allergic as well as contact dermatitis and has been recommended to be applied twice to three times a day [15].

In a study conducted in China, the effect of Mg was studied on contact allergic dermatitis in mice. In that study, the drug was parenteral. Pathologic changes in the mice ears were studied using staining under optical microscope. The results indicated that the ear inflammation and erythema decreased significantly and that specific concentrations of Mg had therapeutic properties for allergic contact dermatitis in the mice [16].

In a study by Pastorfid et al., topical application of zinc chloride spray and Mg hydroxide ointment were studied in patients with abdominal and perineal incisional wounds and it was pronounced decrease in the wound size and recovery duration, better control of infection, and control of clear pain was noted in the patients in comparison to those receiving placebo. In addition, no side effect was observed in the patients [17].

In a study by Shaikh ZI et al., upon treating recurrent melasma using topical 5% Mg ascorbyl phosphate and fluorescent pulsed lighting Asian patients, 65 patients with this disease underwent treatment with 5% Mg ascorbyl phosphate and fluorescent pulsed light for approximately 12 weeks, which contributed to decrease in hypermelanosis in these patients [18].

In a study by Iraj and Rezazadeh to compare the efficacy of topical application of sucralfate and hydrocortisone on diaper dermatitis, 64 one- to 24-month infants with diaper dermatitis were enrolled into the study. A total of 32 patients underwent treatment with sucralfate 4% and 32 patients with hydrocortisone cream. The patients were followed up until complete recovery. The results indicated that topical sucralfate had a similar effect to that of topical hydrocortisone on diaper dermatitis treatment [19].

## CONCLUSION

It was concluded that topical application of this cream could contribute importantly to pain relief and mothers' and infants' comfort because of speedy recovery of the lesion and diaper rash-caused inflammation. Furthermore, mothers should be advised to wash the infants appropriately and change the diaper repeatedly.

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## REFERENCES

- [1] Folster-Holst R, Buchner M, Proksch E. Diaper dermatitis. *Hautarzt*. 2011;62(9):699-708.
- [2] Philipp R, Hughes A, Golding J. Getting to the bottom of nappy rash. ALSPAC Survey Team. Avon Longitudinal Study of Pregnancy and Childhood. *British J Gen Pract*. 1997;47(421):493-97.
- [3] Sryzdy S, Janghorbani M, Ghadi Pasha N. Diaper dermatitis prevalence and risk factors in children under 2 years of kindergarten in 1373 Kerman. *Iran J Dermatol*. 1997;1:24-28. (Persian)
- [4] Panahi Y, Sharif MR, Sharif A, Beiraghdar F, Zahiri Z, Amirchoopani G, et al. A randomized comparative trial on the therapeutic efficacy of topical aloe vera and *Calendula officinalis* on diaper dermatitis in children. *Scientif World J*. 2012;2012:810234.
- [5] Adalat S, Wall D, Goodyear H. Diaper dermatitis-frequency and contributory factors in hospital attending children. *Paediatr Dermatol*. 2007;24(5):483-88.
- [6] Xhaufflaire-Uhoda E, Henry F, Pierard-Franchimont C, Pierard GE. Electrometric assessment of the effect of a zinc oxide paste in diaper dermatitis. *Int J Cosmet Sci*. 2009;31(5):369-74.
- [7] Davies MW, Dore AJ, Perissinotto KL. Topical vitamin A, or its derivatives, for treating and preventing napkin dermatitis in infants. *Cochrance Database Syst Rev*. 2005;(4):CD004300.
- [8] Noonan C, Quigley S, Curley MA. Skin Integrity in Hospitalized Infants and Children: A Prevalence survey. *J paediatrnurs*. 2006;21(6):445-53.
- [9] Society CP. Skin care for your baby. *Paediatr Child Health journal*. 2007;12(3):245-51.
- [10] Ference JD, Last AR. Choosing topical corticosteroids. *Am Fam Physician*. 2009;79(2):135-40.
- [11] Mohammedamin RS, van der Wouden JC, Koning S, van der Linden MW, Schellevis FG, van Suijlekom-Smit LW, et al. Increasing incidence of skin disorders in children? A comparison between 1987 and 2001. *BMC Dermatol*. 2006;6:4.
- [12] Al-Faraidy NA, Al-Natour SH. A forgotten complication of diaper dermatitis: Granuloma gluteale infantum. *J Fam Commun*. 2010;17(2):107-09.
- [13] Proksch E, Nissen H, Bremgartner M, Urquhart C. Bathing in a magnesium-rich Dead Sea salt solution improves skin barrier function, enhances skin hydration, and reduces inflammation in atopic dry skin. *International Journal of Dermatology*. 2005;44(2):151-57.
- [14] Denda M, Katagiri C, Hirao T, Maruyama N. Some magnesium salts and a mixture of magnesium and calcium salts accelerate skin barrier recovery. *Arch Dermatol Res*. 1999;291:560-63.
- [15] Del Rosso JQ, Bhamri S, Michaels B. An Aluminum Magnesium Hydroxide Stearate-based Skin Barrier Protection Cream Used for the Management of Eczematous Dermatitis: A Summary of Completed Studies. *J Clin Aesthet Dermatol*. 2008;1(4):18-21.
- [16] Xu J, Liu J, Peng C, Liu Y, Hu J. Effect of magnesium isoglycyrrhizinate on allergy contact dermatitis (ACD) in mice. *Pub med Article in Chinese*. 2010;35(10):1311-14.
- [17] Pastorfide GB, Gorgonio NM, Ganzon AR, Alberto RM. Zinc chloride spray--magnesium hydroxide ointment dual topical regimen in the treatment of obstetric and gynecologic incisional wounds. *ClinTher*. 1989;11(2):258-63.
- [18] Shaikh ZI, Mashood AA. Treatment of refractory melasma with combination of topical 5% magnesium ascorbyl phosphate and fluorescent pulsed light in Asian patients. *Int J Dermatol*. 2014;53(1):93-99.
- [19] Iraj F, Rezazadeh M. The efficacy of topical sucralfate in comparison with hydrocortisone cream in the treatment of diaper dermatitis: A randomized, double blind clinical trial. *J Dermatol*. 2003;6(1):8-12.

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