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EFFICACY AND SAFETY OF MOMETASONE FUROATE IN CHILDREN WITH ATOPIC DERMATITIS IN KAZAKHSTAN

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Abstract

Background. Atopic dermatitis is a serious chronic skin disease, often aggravated by the presence of microorganisms, which often responds well to strong corticosteroid therapy. However, long-term use of strong topical corticosteroids is associated with side effects such as skin atrophy. The current standard of local anti-inflammatory treatment is topical glucocorticosteroids and calcineurin inhibitors. Mometasone furoate 0.1 percent is a moderate efficacy corticosteroid, which is indicated for the treatment of atopic dermatitis in children. **This research aims** to evaluate the efficacy and safety of mometasone furoate in pediatric patients with atopic dermatitis.

Materials and methods. In this prospective trial, 60 pediatric patients diagnosed with mild to moderate AD were randomly assigned to two separate groups for comparison. The observation group (n=30) received treatment with 0.1% mometasone furoate, while the control group (n=30) underwent standard therapy without mometasone furoate. The study duration was 12 weeks and was conducted at San-Med Service Clinic in Shymkent, Kazakhstan, from December 1, 2024, to February 2025.

Results. Treatment with 0.1% mometasone furoate resulted in a more pronounced reduction in atopic dermatitis severity and greater improvement in quality of life (CDLQI) compared to standard therapy. The safety profile was favorable, with no significant adverse effects. Cortisol levels showed no statistically significant differences between the groups, confirming the absence of systemic effects.

Conclusions. Consistently using a 0.1% mometasone furoate topically to treat mild to moderate atopic dermatitis in children older than 2 years decreased the frequency of relapses and the quantity of mometasone furoate prescribed. It was also safe and well tolerated by patients.

Keywords: *atopic dermatitis, mometasone furoate 0.1%, topical corticosteroids, safety, quality of life, efficacy, pediatric patients*

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Резюме

ЭФФЕКТИВНОСТЬ И БЕЗОПАСНОСТЬ МОМЕТАЗОНА ФУРОАТА У ДЕТЕЙ С АТОПИЧЕСКИМ ДЕРМАТИТОМ В КАЗАХСТАНЕ

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Актуальность. Атопический дерматит - это тяжелое хроническое заболевание кожи, которое часто усугубляется присутствием микроорганизмов и часто хорошо поддается лечению сильнодействующими кортикостероидами. Однако длительное применение сильнодействующих местных кортикостероидов сопровождается побочными эффектами, такими как атрофия кожи. Топические глюкокортикостероиды и ингибиторы кальциневрина являются современным стандартом местной противовоспалительной терапии. Мометазон фуроат 0.1% - это кортикостероид средней эффективности, эффективный при лечении атопического дерматита у детей. **Целью данного исследования** является оценка эффективности и безопасности мометазона фуроата у детей с атопическим дерматитом.

Материалы и методы. В проспективное исследование были включены 60 детей с атопическим дерматитом легкой и средней степени тяжести, которые были рандомизированы на две группы. Группа наблюдения (n=30) получала терапию мометазона фуроатом 0,1%, а контрольная группа (n=30) – стандартное лечение без применения мометазона фуроата. Продолжительность исследования составила 12 недель, и оно проводилось в клинике ТОО «Сан-Мед Сервис» в городе Шымкент, Казахстан, с 1 декабря 2024 года по февраль 2025 года.

Результаты. Терапия 0,1% мометазона фуроатом продемонстрировала более значительное снижение выраженности атопического дерматита и улучшение качества жизни (CDLQI) по сравнению со стандартным лечением. Профиль безопасности был благоприятным, без значимых побочных эффектов. Уровень кортизола оставался без статистически значимых изменений между группами, что подтверждает отсутствие системного воздействия.

Выводы. Лечение легкой и среднетяжелой формы атопического дерматита у детей старше 2 лет последовательным применением 0,1% раствора мометазона фуроата для местного применения значительно уменьшало количество рецидивов и количество назначаемого мометазона фуроата и было безопасным и хорошо переносилось пациентами.

Ключевые слова: *атопический дерматит, мометазон фуроат 0.1%, топический глюкокортикостероид, безопасность, качество жизни, эффективность, дети.*

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Түйіндеме

ҚАЗАҚСТАНДАҒЫ АТОПИЯЛЫҚ ДЕРМАТИТІ БАР БАЛАЛАРДАҒЫ МОМЕТАЗОН ФУРОАТЫНЫҢ ТИІМДІЛІГІ МЕН ҚАУІПСІЗДІГІ

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Кіріспе. Атопиялық дерматит- ол көбінесе микроорганизмдердің болуымен асқынатын және жиі күшті кортикостероидтармен емдеуге жақсы жауап беретін ауыр, созылмалы тері ауруы. Дегенмен, күшті жергілікті кортикостероидтарды ұзақ уақыт қолдану тері атрофиясы сияқты жанама әсерлермен бірге жүреді. Жергілікті глюкокортикостероидтар мен кальциневрин ингибиторлары жергілікті қабынуға қарсы терапияның заманауи стандарты болып табылады. Мометазон фуроаты 0.1% - бұл балалардағы атопиялық дерматитті емдеуде тиімді орташа күштілігі бар кортикостероид. **Бұл зерттеудің мақсаты** атопиялық дерматитпен ауыратын балалардағы мометазон фуроатының тиімділігі мен қауіпсіздігін бағалау болып табылады.

Материалдар мен әдістер. Перспективалық зерттеуге екі топқа рандомизацияланған жеңіл және орташа атопиялық дерматиті бар 60 бала қатысты. Бақылау тобы (n=30) мометазон фуроат терапиясын 0,1%, ал негізгі тобы (n=30) мометазон фуроатын қолданбай стандартты ем қабылдады. Зерттеудің ұзақтығы 12 аптаны құрады және ол 2024 жылғы 1 желтоқсаннан 2025 жылғы ақпанға дейін Шымкент қаласындағы "Сан-Мед Сервис" ЖШС клиникасында жүргізілді.

Нәтижесі. 0,1% мометазон фуроат терапиясы стандартты емдеумен салыстырғанда атопиялық дерматиттің ауырлығының айтарлықтай төмендеуін және өмір сапасының жақсаруын (CDLQI) көрсетті. Қауіпсіздік профилі маңызды жанама әсерлерсіз қолайлы болды. Кортизол деңгейі топтар арасында статистикалық маңызды өзгеріссіз қалды, бұл жүйелік әсердің жоқтығын растайды.

Қорытынды. 2 жастан асқан балалардағы атопиялық дерматиттің жеңіл және орташа түрін 0,1% жергілікті мометазон фуроат ерітіндісін қолдану арқылы қайталанатын және тағайындалған мометазон фуроатының көп мөлшерде қолдануын айтарлықтай азайтты және пациенттер үшін қауіпсіз, әрі жақсы төзімді болды.

Түйін сөздер: *атопиялық дерматит, мометазон фуроат 0.1%, жергілікті кортикостероид, қауіпсіздік, өмір сапасы, тиімділік, балалар.*

Дәйексөз үшін:

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Introduction

Atopic dermatitis (AD) is a chronic, recurrent inflammatory skin disease characterised by intense itching and distinctive inflammatory changes. AD has a pronounced negative impact on the patient's quality of life, as well as on the emotional and psychosocial state of his family [3]. Atopy is defined as a syndrome that can be described as a genetically determined disorder of the maturation of the immune system of unknown origin. It is characterised by an increased tendency to form IgE antibodies and is often associated with a personal or family history of atopic dermatitis, allergic rhinitis or asthma [5, 6, 14]. The first manifestation of the atopic march begins with AD. Atopic dermatitis is usually seen during the first 6 months of life and persists into adulthood in 25% of the population. The incidence of AD has increased significantly in recent decades, especially in high-income countries [9]. Thus, preventing even a small percentage of cases of AD can bring significant benefits to individual patients, the healthcare system, and socio-economic structures [4, 8, 21]. Traditionally, the early onset of AD compared to other allergic diseases, such as allergic rhinitis and asthma, has led to the assumption that AD progresses into allergic rhinitis and then into asthma in a linear sequence [1, 16]. Allergic asthma (AA) and allergic rhinitis (AR) represent the final stage of the atopic march.

The pathophysiological mechanisms of atopic dermatitis (AD) remain to be fully elucidated. Numerous studies have confirmed that dysfunction of the skin barrier, in combination with impaired immune regulation, plays a key role in its pathogenesis [2, 13, 15]. According to an alternative hypothesis, AD is caused by dysregulation of the immune response, manifested by hyperactivation of Th2-mediated inflammation and overexpression of type II cytokines such as IL-4 and IL-13 [10]. In addition, there is preliminary evidence indicating the role of genetic factors in the pathogenesis of atopic dermatitis, in particular, that carriers of mutations in the filaggrin gene are highly susceptible to environmental influences, which contributes to the development of the disease [12].

Topical corticosteroids have been proven to be highly efficient in the treatment of atopic dermatitis; however, their frequent and prolonged utilisation, particularly in paediatric populations, is associated with numerous adverse effects. Mometasone furoate is a medium-efficacy corticosteroid that is indicated for the relief of inflammatory and pruritic manifestations of atopic dermatitis [17, 20]. Despite the existence of a significant number of international studies on the efficacy and safety of Mometasone furoate, information on its use in children with atopic dermatitis in Kazakhstan remains limited. **The objective** of the present study is to evaluate the efficacy and safety of Mometasone furoate in children with atopic dermatitis in Kazakhstan.

Materials and methods

Study design

The prospective study included 60 children with mild to moderate atopic dermatitis, divided into two groups: 30 patients in the observation group who received 0.1% Mometasone furoate therapy, and 30 patients in the control group who received standard treatment without Mometasone furoate. The study duration was 12 weeks and was conducted at the clinic of “San-Med Service” LLP in Shymkent, Kazakhstan, from December 1, 2024, to February 2025.

Study population

The study included children aged 2 to 18 years with a confirmed diagnosis of mild to moderate atopic dermatitis on the SCORAD scale (Scoring Atopic Dermatitis).

Inclusion criteria:

1. Demographic criteria:

- Age: 2-18 years’ old
- Gender: girls and boys

2. Diagnostic criteria:

- Confirmed diagnosis of atopic dermatitis following the Hanifin and Rajka criteria and international guidelines (EAACI, AAD).
- Mild and moderate degree of atopic dermatitis according to SCORAD (15-45 points).
- Complete blood count test (eosinophilia)
- Total IgE
- With diagnosed rhinitis, a nasal cytology

3. Informed consent:

Signed informed consent of the parents/guardians for the child's participation in the study.

Treatment methods: patients were randomized into two groups:

1. Observation group: topical application of mometasone furoate 0.1% 1 time per day on the affected skin areas.
2. Control group: the use of antihistamines. Both groups also used emollients at least twice a day.

Exclusion criteria:

1. Diseases and conditions affecting the results of the study:

- Severe form of atopic dermatitis (SCORAD >50).
- Presence of secondary skin infection (bacterial, fungal, viral, including herpes, molluscum contagiosum).
- The presence of other chronic skin diseases such as psoriasis, ichthyosis, and contact dermatitis.
- Severe immunodeficiency (primary and secondary immunodeficiencies).

2. The use of other treatment methods:

- Systemic therapy (glucocorticosteroids, immunosuppressant, biologics) 4 weeks before the start of the study.
- Topical corticosteroids or calcineurin inhibitors 7 days before the start of the study.

3. Allergic reactions and individual intolerance:

- Allergy or hypersensitivity to the components of the drug mometasone furoate.

4. Other medical and social factors:

• Decompensated chronic diseases (for example, severe bronchial asthma, uncontrolled diabetes mellitus).

• Parents/guardians' refusal to participate in the study.

Effectiveness assessment:

The effectiveness of therapy was evaluated at weeks 2, 4, 8, and 12 according to the following criteria:

- Dynamics of the SCORAD index;
- Assessment of the severity of itching on a Visual Analog Scale (VAS) (0-10 points);
- Improving the quality of life according to the CDLQI (Children's Dermatology Life Quality Index) questionnaire;
- The level of cortisol in the blood.

Safety assessment: Side effects were recorded at each visit, including:

- Development of skin atrophy (assessment by dermatoscopy);
- The appearance of telangiectasia;
- The development of hypopigmentation;
- Systemic side effects (analysis of blood cortisol levels in patients using the drug for more than 4 weeks).

Statistical analysis

The data was analyzed using Excel 2013. The Student's t-test (for parametric data) and the Mann-Whitney U Test (for nonparametric data) were used to assess the differences between the groups. The significance of the differences was considered significant at $p<0.05$.

Ethical aspects

The study was conducted in accordance with the Helsinki Declaration and approved by the local ethics committee. All parents signed an informed consent for their children to participate in the study.

Results

A total of 60 children with mild and moderate atopic dermatitis were included in the study, which were divided into two groups. In the observation group (group A, n=30), patients received 0.1% Mometasone furoate therapy, and in the control group (group B, n=30), standard treatment with antihistamines and emollients was performed without the use of Mometasone furoate. In the group receiving Mometasone furoate, there were 12 boys (40%) and 18 girls (60%), while in the control group not receiving Mometasone furoate, there were 17 boys (56.67%) and 13 girls (43.33%).

The mean age of patient's in-group A was 10.27±6.61 years, and in group B was 4.77±4.55 years. 46.67% of patients in group A and 86.67% of patients in group B were in the age group from 1 to 10 years, and 53.33% and 13.33%, respectively, were in the age group over 10 years (see Table 1).

Table 1.

Distribution of patients by age and mean age.

Age in years	Group A (n=30)	Group B (n=30)
from 1 to 10	14 (46,67)	26 (86.67)
> 10	16 (53.33)	4 (13.33)
Total	30 (100.00)	30 (100.00)
Mean± SD	10.27±6.61	4.77± 4.55

A complete blood count test was performed to assess the level of eosinophils. In the group receiving Mometasone furoate, the average level of eosinophils was 5.26±3.35%, while in the control group, this indicator was 5.13±3.12%. There were no significant differences between the control and observation groups. The data obtained indicate that there is no significant effect of Mometasone furoate on eosinophilia.

At baseline, the average overall severity score of atopic dermatitis was 31.00 ± 7.40 in group A and 26.33 ± 9.14 in group B.

• At the first control examination, the indicators decreased to 25.00 ± 8.23 in group A and 23.54 ± 8.86 in group B.

• At the second control examination, the indicators were 16.23 ± 12.74 in group A and 20.62 ± 8.06 in group B.

• At the final control examination, the scores decreased to 11.87 ± 8.04 in group A and 18.83 ± 7.05 in group B ($p>0.05$, statistically insignificant).

The total percentage of reduction in the severity of the disease from baseline to final examination:

• Group A: 61.71%

• Group B: 28.49% (see Table 2).

Table 2.

Average SCORAD (general assessment of the severity of atopic dermatitis) at different stages of follow-up.

	Group A	Group B	p value
Initial	31.00 ± 7.40	26.33 ± 9.14	0.05
1st examination	25,00 ± 8,23	23.54 ± 8.86	<0.05
2nd examination	16,23 ± 12,74	20.62 ± 8,06	<0.05
Last checkup	11,87 ± 8,04	18.83 ± 7.05	<0.05
Percentage decrease from baseline to last examination	61.71%	28.49%	

The study analyzed cortisol levels in patients of both groups. In the group receiving Mometasone furoate, the average cortisol level was 287.59±110.11 nmol/l, while in the control group this indicator was 205.33±98.22 nmol/L. Statistical analysis did not reveal significant differences between groups A and B, which indicates that there was no significant effect of Mometasone furoate on cortisol levels in this study.

According to the diagnostic criteria of Hanifin and Rajka criteria, all study participants were evaluated for itching. In our study, 22 patients (73.3%) in the momatesone furoate group and 21 patients (70.0%) in the control group had localized itching, while 8 patients (26.7%) and 9 patients (30.0%), respectively, experienced generalized itching.

According to the severity of itching, the acute form was recorded in 15 patients (50.0%) in the Mometasone furoate group and in 14 patients (46.7%) in the control group, while the chronic form was observed in 15 patients (50.0%) and 16 patients (53.3%), respectively. Other common symptoms were dry skin, observed in 22 patients (73.3%), and inflamed skin, detected in 4 patients (13.3%) at the initial examination.

After a 12-week treatment period, 26 patients (86.67%) in the Mometasone furoate group achieved good control of atopic dermatitis symptoms compared to 18 patients (60.0%) in the control group. At the same time, 4 patients (13.33%) in the Mometasone furoate group and 12 patients (40.0%) in the control group continued to experience uncontrolled symptoms, which indicates a higher effectiveness of treatment in the Mometasone furoate group.

The mean (± SD) CDLQI score in the study population was 8.42 (± 3.57) out of 30. In the observation group, the average CDLQI score was 7.90 (± 3.42), while in the control group it was 9.14 (± 3.69), which indicates a tendency towards a better quality of life in children receiving Mometasone furoate. Among all participants, 18 children

(60.0%) in the observation group and 16 children (53.3%) in the control group experienced a moderate effect of AD on their quality of life. Only 1 child (3.3%) in the observation group and 1 child (3.3%) in the control group noted that the disease had an extremely strong impact on their daily lives. The analysis of individual CDLQI domains showed that Q1 (itching, burning, painful sensations on the skin) had the greatest impact on the quality of life, with an average (± SD) score of 1.83 (± 0.78) out of 3. In the follow-up group, 43.3% of children reported that itching and burning significantly worsened their quality of life, while in the control group this figure was 36.7%. Q6 (avoiding swimming or playing sports) had the least impact on quality of life, with an average score of 0.27 (± 0.48). The majority of participants (76.7% in the observation group and 71.7% in the control group) noted that atopic dermatitis did not affect their participation in sports. Similarly, the effect of atopic dermatitis on Q8 (name-calling) was low, with an average score of 0.35 (± 0.50) out of 3, while 66.7% of children in the observation group and 64.3% in the control group reported that this factor did not affect their quality of life. Regarding Q4 (influence on clothing/shoe choice), 40.0% of children in the observation group and 34.3% in the control group noted that atopic dermatitis had a slight effect on their clothing choice, with an average (± SD) score of 1.76 (± 0.92). A similar trend was observed concerning sleep disorders (domain Q9). 53.3% of children in the observation group and 50.0% in the control group noted that sleep disorders slightly worsened their quality of life, with an average score of 1.47 (± 0.84) (see Diagram 1).

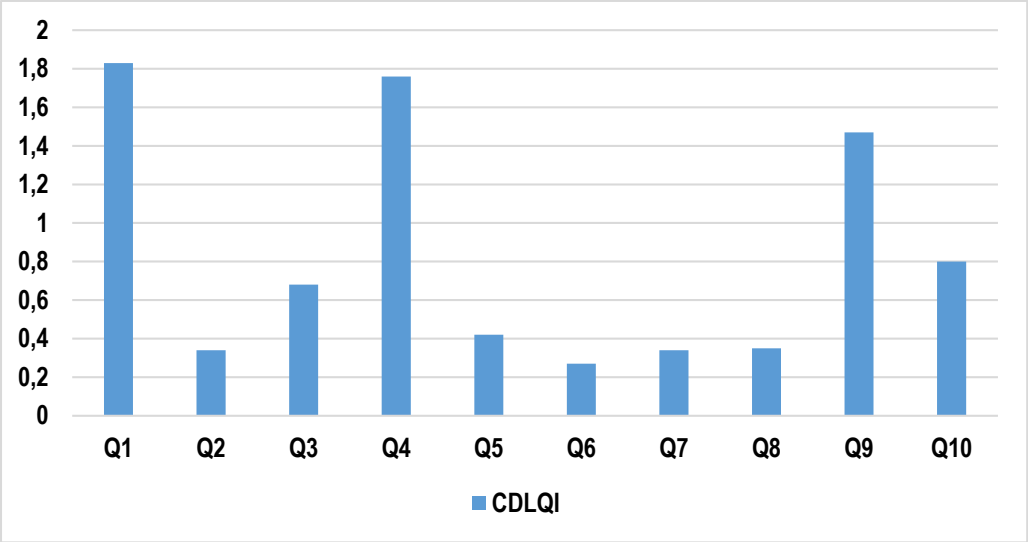

Diagram 1. Distribution of symptoms/effects on quality of life by CDLQI.

Discussion

This prospective study evaluated the efficacy and safety of Mometasone furoate in children with atopic dermatitis in Kazakhstan. The results of the study showed a significant clinical improvement in most patients treated with Mometasone furoate, as well as a high safety profile and good tolerability of this drug. These data emphasize the importance of using Mometasone furoate as the main element of therapy for atopic dermatitis in children, especially in regions with a high incidence rate.

Clinical improvements in patients were manifested in a significant reduction in the severity of the main symptoms of atopic dermatitis, including itching, erythema, skin infiltration and the presence of scratching. Most of the children showed a reduction in the area of the affected skin and an improvement in the quality of life, which corresponds to the results of international studies. Similar studies by *Yang et al.* It has been shown that the consistent use of Mometasone and Crisaborol significantly reduces the frequency of relapses in children with mild and moderate forms of AD [22]. In group B, who received standard therapy using antihistamines and emollients without the use of Mometasone furoate, there was also a decrease in SCORAD scores. This indicates the importance of basic treatment in the complex therapy of atopic dermatitis. However, the degree of reduction in the severity of skin manifestations was less significant compared to group A, where Mometasone furoate was used. These differences highlight the key role of topical corticosteroids in controlling inflammation in atopic dermatitis. In other similar studies, Mometasone has demonstrated significant efficacy in reducing the severity of atopic dermatitis, as evidenced by improved SCORAD scores in clinical trials [18,11]. The data obtained from our study indicate that there is no significant effect of Mometasone furoate on eosinophilia. However, a study by *Kato et al.,* [7], *Tsuda et al.,* [19] shows that Mometasone furoate, a local corticosteroid, significantly affects the level of eosinophils and reduces the severity of the clinical picture and associated eosinophilic activity, as evidenced by a decrease in serum levels of eosinophilic cationic protein (ECP), markers of eosinophil activation and inflammation in patients with atopic dermatitis. The Quality of Life Index for Children with Dermatological Diseases (CDLQI) is an essential tool for assessing the quality of life of children with atopic dermatitis (AD), especially when evaluating the effectiveness of treatments such as mometasone. Studies show that AD significantly affects the quality of life of children, with varying degrees of severity correlating with CDLQI indicators. In our study, the average CDLQI score in the observation group was 7.90 (± 3.42), while in the control group it was 9.14 (± 3.69), which indicates a tendency towards a better quality of life in children receiving

Mometasone furoate. It should be noted that there are very few studies in the literature evaluating the effect of Mometasone furoate using the Quality of Life Index of Pediatric Dermatology (CDLQI), which underlines the importance of further observations and research in this area.

The statistical analysis did not reveal significant differences between the control and the main group in terms of cortisol levels, which indicates that there is no significant effect of Mometasone furoate on adrenal function in children with atopic dermatitis in this study. This corresponds to the available literature data, although there is little information about the effect of Mometasone on cortisol levels in children, and further study of this issue is required.

Limitations

Due to the fact that our study is the first phase of the work, it has a number of limitations that should be taken into account when interpreting the results. First, the relatively small number of patients in each group limits the statistical power of the analysis and may prevent the identification of significant differences between the groups. Secondly, the duration of follow-up was only 12 weeks. This period may not be sufficient to identify possible long-term effects of therapy, such as persistent changes in cortisol levels or the development of chronic adverse reactions. Thirdly, this study did not include a direct comparison of Mometasone furoate with other topical corticosteroids. Consequently, we cannot draw conclusions about its relative advantage or comparability with alternative medications

These limitations emphasize the need for additional, larger, and longer-term studies to confirm and refine our findings.

Further studies are planned to involve a greater number of patients and a longer follow-up period. This will facilitate not only the confirmation of the current results but also the detailed analysis of mometasone furoate therapy's effect on the prevention of subsequent allergic diseases in children with atopic dermatitis. Furthermore, future research should incorporate direct comparive testing of Mometasone furoate against other topical corticosteroids to definitively establish its clinical advantages over alternative drugs.

Conclusion

Based on the data obtained, it is concluded that Mometasone furoate 0.1% therapy is effective and safe in the treatment of atopic dermatitis in children. In the observation group administered Mometasone furoate, there was a significant decrease in the severity of clinical manifestations of the disease, which was comparable to the dynamics in the control group. However, the efficacy of treatment with Mometasone furoate was superior to that observed in the control group, as evidenced by a more pronounced decrease in the SCORAD index and an enhancement in the quality of life of patients, as assessed by the CDLQI (Children's Dermatology Life Quality Index). The safety profile of Mometasone furoate was satisfactory, with no significant side effects. Furthermore, no statistically significant difference in cortisol levels was observed between the groups, thereby confirming the absence of a systemic effect of therapy. Further studies involving a large number of patients and a longer follow-up period are needed to confirm the results obtained and to evaluate in more detail the long-term efficacy and safety of treatment.

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