

EVALUATION OF THE EFFICACY OF A MEDICAL DEVICE REPAIRING EMOLLIENT CREAM IN ADULTS WITH MILD TO MODERATE HEAD AND NECK ATOPIC DERMATITIS

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INTRODUCTION

Head and neck atopic dermatitis (HNAD) is probably the most characteristic form of adult AD, with a strong impact on quality of life. The management of these sensitive areas, often exposed to environmental triggers is particularly challenging and specific datas on this location are sparse. The objective of the study was to evaluate the efficacy of a medical device repairing emollient cream in this indication.

MATERIAL & METHODS

PATIENTS

19 Adults (from 22 to 47 years old) with HNAD were included in a multicentric exploratory clinical trial in Germany in 2021-2022. They applied the product twice a day for 29 days. 37 % of them reported more than 6 HNAD flare-up per year.

MAIN INCLUSION CRITERIA

- Mild to moderate HNAD with 3 ≤ Local SCORAD ≤ 10 ; with
 - Mild to severe Xerosis intensity
 - Mild to moderate Erythema intensity
 - Absent to moderate Lichenification intensity
 - Absent to mild Oedema/papulation, Oozing/crusts, Excoriation intensity

MAIN EXCLUSION CRITERIA

- Topical treatments of HNAD within 2 weeks before the inclusion visit
- Phototherapy within 4 weeks before the inclusion
- Systemic immunosuppressive treatment within 4 weeks
- Systemic biological treatments within 12 weeks before the inclusion

MAIN EVALUATION CRITERIA

CLINICAL PARAMETERS

- Local SCORAD and Patient Oriented (PO) -SCORAD
- HNAD extent
- Local investigators’ and patients’ global assessments: IGA and PGA
- Pruritus and skin pain intensities (average over the past 24 hours on numerating rating scale/ NRS)

QUALITY OF LIFE (QoL) PARAMETERS

- Dermatology Life Quality Index (DLQI)
- Chronic Itch Burden Scale – 20

BIOMETRIC PARAMETERS

- Hydration Index /HI
- Trans-Epidermal Water Loss/TEWL

SAFETY

RESULTS

LOCAL SCORAD

→ At D29, significant decrease of mean L PO–SCORAD of - 46.5% (p<0.001)

LOCAL PO - SCORAD

→ At D29, significant decrease of mean L PO–SCORAD of - 46.5% (p<0.001)

HNAD EXTENT

→ At D29, significant decrease of mean HNAD Extent of - 32.8 % (p<0.001)

PRURITUS INTENSITY
(AVERAGE OVER THE PAST 24 HOURS)

→ At D29, significant decrease of mean pruritus and pain scores of - 31.8% and - 40.4% respectively (p<0.05)

PAIN INTENSITY
(AVERAGE OVER THE PAST 24 HOURS)

→ At D29, significant decrease of mean pruritus and pain scores of - 31.8% and - 40.4% respectively (p<0.05)

HNAD EVOLUTION

IGA :
At D29, an improvement of HNAD was assessed by investigators for **58 % of the patients**

PGA :
At D29 , an improvement of HNAD was assessed by **53 % of patients themselves**

QoL – DLQI

→ At D29, Significant decrease of mean DLQI score of - 38.2 % (p<0.05)

QoL – CHRONIC ITCH BURDEN SCALE

→ On D1, 84% of subjects reported scratching until feeling pain, and among them, 74% reported an improvement of the symptom at D29

→ On D1, 79% of subjects reported to be stressed because of itching , and among them, 68% reported an improvement of the symptom at D29

SAFETY

Nine subjects had dermatological adverse events (DAEs) suspected to be related to the product (mostly functional signs as pruritus, skin pain). For 7 of them, DAEs were also suspected to be related to HNAD worsening.

BIOMETRIC PARAMETERS

→ IH : Increase of the mean HI of 27.4% at D29 compared to D1 (p>0.05)

→ TEWL : Decrease of the mean TEWL of -10.5% at D29 compared to D1 (p>0.05)

ILLUSTRATIVE IMAGES

Hypothetical patient. Illustrative image generated by IA and based on clinical data (mean HNAD Extent and LOCAL SCORAD sub parameters : erythema, xerosis and desquamation.) . Results may vary depending on the patient.

CONCLUSION

The results of this study highlight the benefit of a medical device repairing emollient cream in head and neck atopic dermatitis. Despite the pandemic context during the study, including potential aggravating factors of HNAD (stress, wearing of masks, ...), a significant effect of the product on clinical parameters and quality of life was demonstrated.