

AN INVESTIGATION OF THE SKIN BARRIER RESTORING EFFECTS OF A CREAM CONTAINING CERAMIDES IN A MULTI VESICULAR EMULSION IN PEOPLE WITH DRY, ECZEMA-PRONE, SKIN:

THE RESTORE STUDY

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INTRODUCTION

- Disruption of the skin barrier leads to skin dryness and is an underlying cause of eczema (dermatitis)¹
- Management of dry skin conditions involves the regular and liberal use of moisturisers (emollients)²
- Moisturisers exhibit very different properties, yet there is limited evidence that one moisturiser is better than another³
- In 2018 the UK National Health Service (NHS) prescribed 8 million moisturising creams at a cost of £50 million (GBP), of which 52% were simple emollient creams (see table)⁴
- The CeraVe cream and lotion contain humectants and skin lipids with slow-release multi-vesicular emulsion (MVE) technology to deliver longer-lasting skin hydration⁵

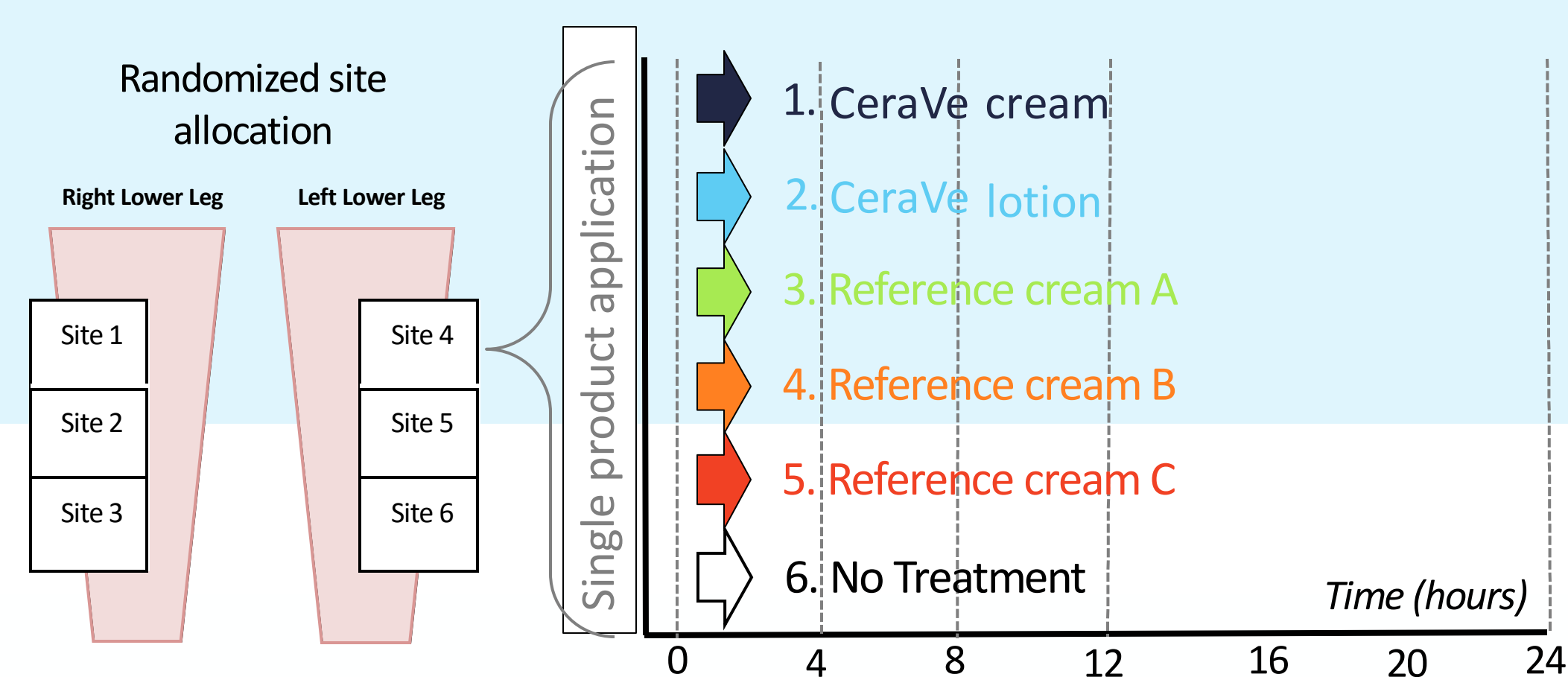
AIM:
To investigate the effects of CeraVe moisturising cream and lotion designed specifically to support skin barrier restoration compared to a panel of common emollient creams.

THE TEST PRODUCTS:

INGREDIENT PROPERTY	COMMON EMOLLIENT CREAMS (reference creams A-C)	CERAVE CREAM AND LOTION (containing ceramides in multi vesicular emulsion)
Emollient/occlusive	Liquid Paraffin, White Soft Paraffin, Cetostearyl Alcohol or Cetearyl Alcohol	Petrolatum, Dimethicone, Cetearyl Alcohol, Cetyl Alcohol, Cetearth-20, Behentrimonium Methosulfate
Humectant		Glycerin & Sodium Hyaluronate
Barrier-reinforcing physiologic lipids		Caprylic/Capric Triglyceride, Ceramide NP, AP & EOP, Phytosphingosine, Cholesterol
Anti-oxidant		Tocopherol
Other ingredients	Cetomacrogol or Polysorbate 60, Chlorocresol or Phenoxyethanol, Phosphoric Acid, Sodium (Dihydrogen) Phosphate, Purified Water	Sodium Lauroyl Lactylate, Phenoxyethanol, Ethylhexylglycerin, Potassium Phosphate, Disodium EDTA, Dipotassium phosphate, Xanthan Gum, Carbomer, Purified Water

PHASE 1

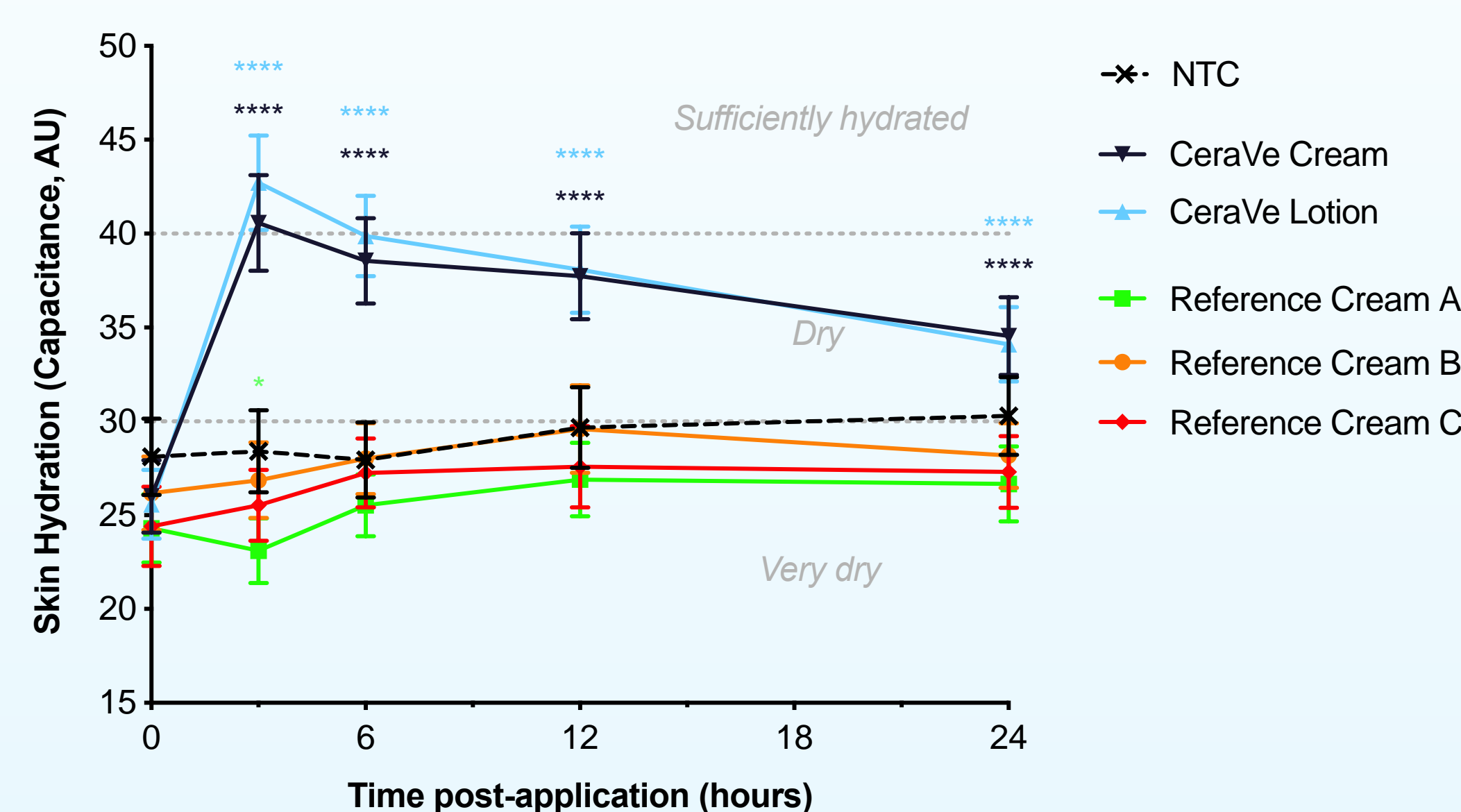
How much and for how long do the test products moisturize the skin compared to currently used emollient creams?



STUDY DESIGN: A single application test was conducted in 22 adults aged 20-66 years of age with dry skin and a history of eczema. Hydration was measured at timed intervals using a Corneometer (C&K, Germany).

CeraVe moisturisers significantly increased skin hydration for more than 24 hours after a single application

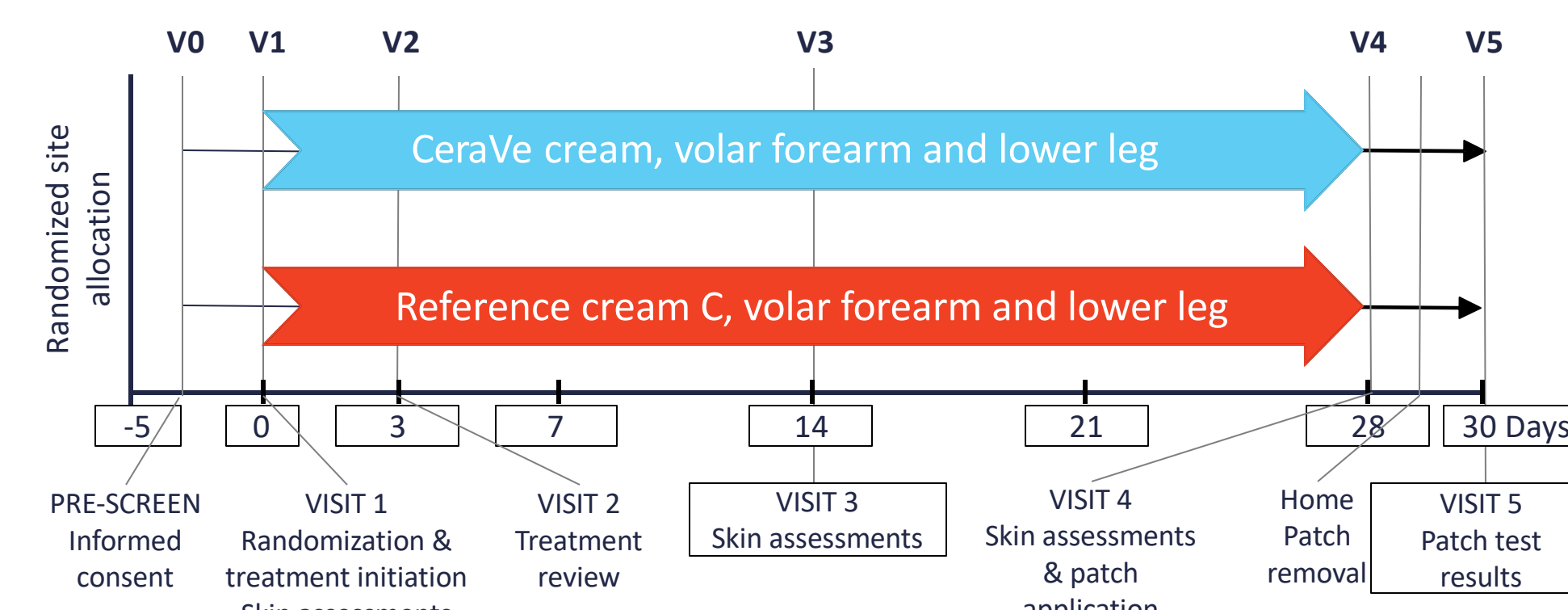
- By comparison the simple emollients tested imparted insignificant levels of hydration
- Equivalent hydration efficacy was observed between CeraVe cream and lotion preparations



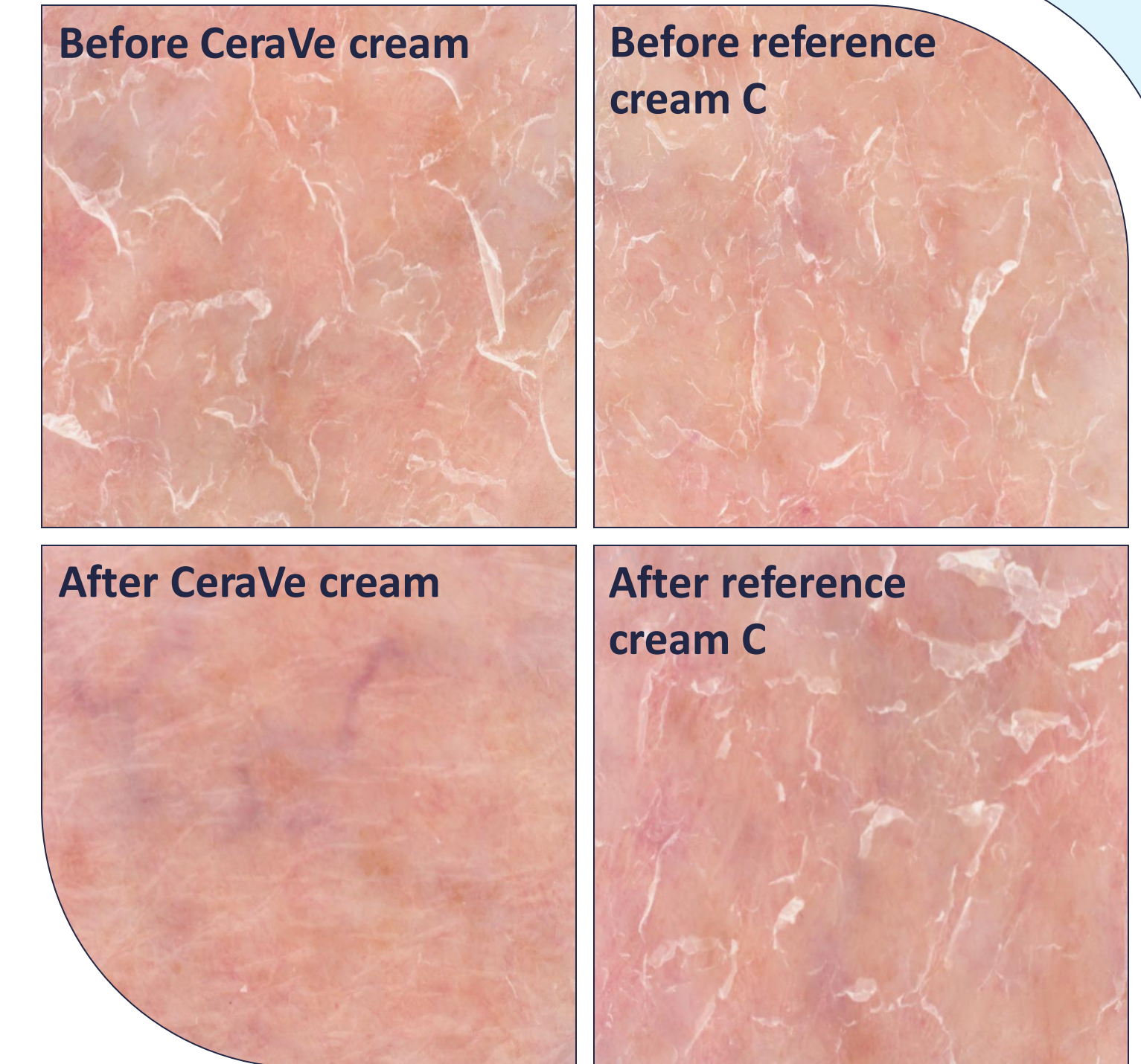
RESULTS: The effect of the 6 treatment conditions on skin hydration, measured as capacitance, over 24 hours. Baseline measurements (0 hours) were taken prior to a single application of the investigational products. NTC, no treatment control. Error bars indicate SEM. Asterisks indicate the results of a Dunnett's post-test (subsequent to ANOVA) comparing each treatment to the NTC at each timepoint independently (*p<0.05, ****p<0.0001).

PHASE 2

Under normal use conditions is CeraVe cream superior to currently used dry skin treatments?

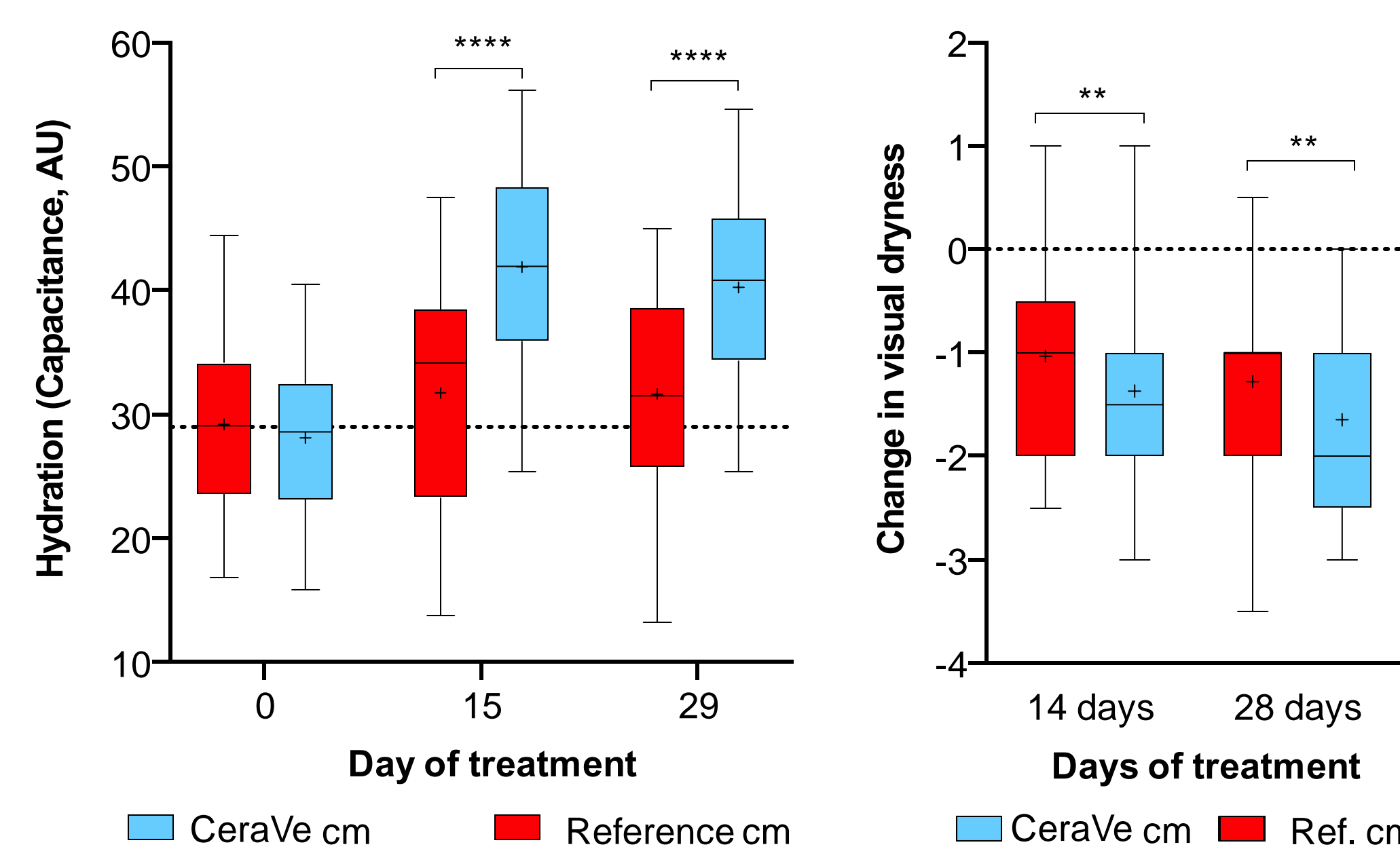


STUDY DESIGN: a double-blind intra-subject-controlled study, wherein 34 participants aged 20-89 with dry skin and a history of eczema underwent 4 weeks twice daily treatment with CeraVe cream and a reference cream C on the forearms and lower legs (randomized allocation to either right or left side). Equal amounts of product were used: 129g test cream and 133g reference cream C.



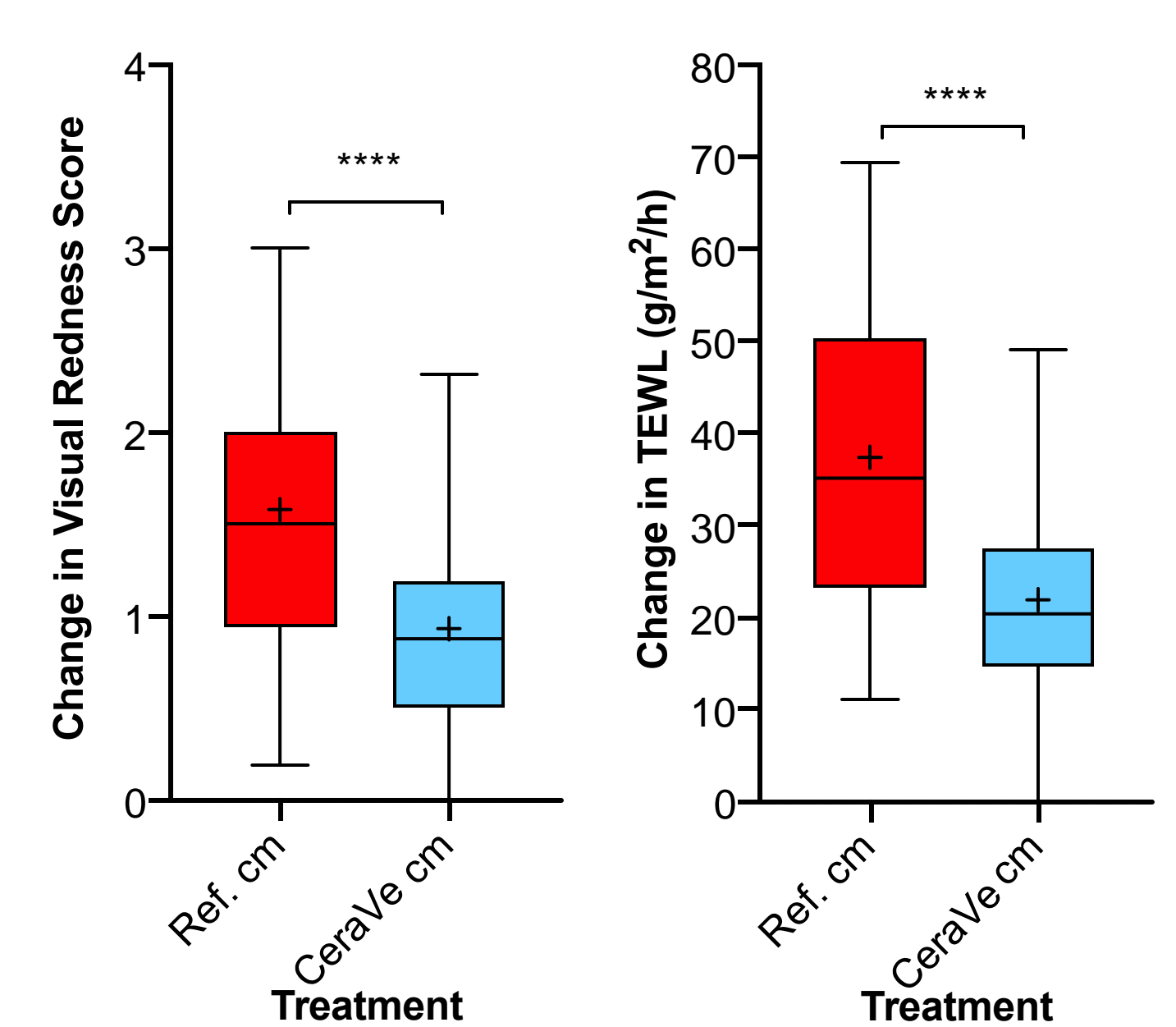
SKIN IMAGES at 50x magnification from a 72 year old male participant with very dry skin at baseline

CeraVe cream delivers sustained increases in skin hydration that effectively treats dry skin



SKIN HYDRATION AND VISUAL DRYNESS at the lower legs before during and after treatment (12-16 h after last application). Boxes indicate the median, 25th and 75th percentiles, with '+' for the mean and whiskers indicating the 5-95th percentiles. There was a significant difference between the effects of the treatments on hydration and dryness. Asterisks indicate the results of pairwise comparison at each time point (**p<0.01, ****p<0.0001).

Pre-treatment with CeraVe cream protects against skin irritation



SKIN SENSITIVITY after 28-days treatment. Change (Day 30-day 29) in visual redness/erythema and transepidermal water loss (TEWL) after 1% sodium lauryl sulphate (SLS) patch (applied for 24h). Boxes indicate the median, 25th/75th percentiles, with '+' for the mean and whiskers for the 5-95th percentiles. ****Results of a pairwise comparison (p<0.0001).

CONCLUSIONS

- CeraVe cream displays **superior moisturising efficacy** compared to reference cream C and similar common emollient creams used to treat dry skin
- The MVE slow-release technology contributes to long-lasting hydration (>24 h), and will reduce the need for the very frequent applications (3-4 times per day) currently recommended^{2,5}
- CeraVe cream **protects against skin irritation**, and potentially allergen challenge
- The skin moisturising and protecting properties of CeraVe cream are associated with **reinforcement of the skin barrier** (data not shown & reference 6)
- By reinforcing the skin barrier CeraVe products may help **maintain healthy skin**³

REFERENCES: (1) Danby SG. Curr Probl Dermatol 2016; 49: 47-60. (2) PCDS In: Guidelines, Vol. 39: 2009; 399-402. (3) van Zuuren EJ et al. Cochrane Database of Systematic Reviews 2017. (4) Prescription Cost Analysis 2018, Prescribing and Primary Care Services. 2019. (5) Zeichner JA, Del Rosso JQ. J Clin Aesth Dermatol 2016; 9: 26-32. (6) Loden M. Arch Dermatol Res 1996; 288: 103-7.

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