KURZPROTOKOLL
MC2-01-C6

Wissenschaftl. Titel	A Randomised, Open-label, Maximal Use Trial, Evaluating the Pharmacokinetic Profile of Active Ingredients and Their Metabolites After Application of MC2-01 Cream Compared With Active Comparator in Subjects With Extensive Psoriasis Vulgaris
Kurztitel	MC2-01-C6
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig
Studienphase	Phase II
Erkrankung	Haut: Schuppenflechte (Psoriasis)
Einschlusskriterien	- Have provided written informed consent - Generally healthy males or non-pregnant females, of any race or ethnicity, who are at least 18 years of age at the time of screening - At Visit 1/Day 0, have a clinical diagnosis of plaque psoriasis (psoriasis vulgaris) of at least 6 months duration involving scalp and body (trunk and/or limbs) that is amenable to topical treatment with a maximum of 100 g of trial medication per week - Have a Physician's Global Assessment [PGA] of severity of at least moderate on the trunk, limbs and/or scalp, at Visit 1/Day 0 - Have a treatment area between 20% and 30% of the body surface area [BSA] on the trunk, limbs and/or scalp, excluding psoriatic lesions on the face, genitals, and intertriginous areas, at Visit 1/Day 0
Ausschlusskriterien	- Current diagnosis of unstable forms of psoriasis - Other inflammatory skin disease in the treatment area - Pigmentation, extensive scarring, pigmented lesions or sunburn in the treatment areas - Planned exposure to natural or artificial sunlight - Phototherapy and ultraviolet B radiation within 4 weeks prior to Visit 1/Baseline and during the trial - Current or past history of hypercalcemia, vitamin D toxicity, severe renal insufficiency, or severe hepatic disorders - Oral calcium supplements, vitamin D supplements, bisphosphonates or calcitonin within 4 weeks prior to Visit 1/Day 0 during the trial period - Planned initiation of, or changes to concomitant medication that could affect calcium metabolism during the trial - Planned initiation of, or changes to, concomitant estrogen therapy during the trial - Strong systemic cytochrome P450 3A4 (CYP 3A4) inhibitors within 4 weeks prior to Vist 1/Day 0 and during the trial period - Use of topical treatments, except for emollients and non-medicated shampoos, with a possible effect on psoriasis within 2 weeks prior to Visit 1/Day 0 and during the trial period - Systemic treatment with biological therapies - Initiation of, or expected changes to, concomitant medication that may affect psoriasis during the trial period - Depression and endocrine disorders known to affect cortisol levels or HPA axis integrity, non-nocturnal sleep patterns - Systemic medication that suppresses the immune system within 4 weeks prior to the Visit 1/Day 0 and during the trial period - Clinical signs of skin infection with bacteria, viruses, or fungi - Known human immunodeficiency virus [HIV] infection; - Known or suspected of hypersensitivity to any component of the test product or reference product

	- Any chronic or acute medical condition that may pose a risk to the safety of the subject, or may interfere with the assessment of safety or efficacy in this trial
Alter	18 Jahre und älter
Prüfzentren	**Klinik für Dermatologie, Venerologie und Allergologie** (Rekrutierung beendet) Theodor-Stern-Kai 7 60590 Frankfurt am Main Jana Sawtschuk
Sponsor	MC2 Therapeutics
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03462927 (primäres Register) EudraCT 2018-000685-12