INM-755 Cream on Epidermal Wounds

Gepubliceerd: 22-06-2020 Laatst bijgewerkt: 15-05-2024

This study is exploratory and no formal hypothesis is set.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28723

Bron
NTR

Verkorte titel
CHDR1944

Aandoening

Epidermolysis Bullosa

Ondersteuning

Primaire sponsor: InMed Pharmaceuticals Inc.
Overige ondersteuning: InMed Pharmaceuticals Inc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Tolerability / safety endpoints
• Incidence of local and systemic treatment-emergent adverse events (TEAEs)
• Changes in vital signs, ECG, safety laboratory tests, and local tolerability assessments
Wound healing endpoints
• Wound characteristics by LSCI, OCT, TEWL, multispectral and 3D photography

• Status of wound closure over time

Toelichting onderzoek

Achtergrond van het onderzoek

INM-755 is being developed for dermal application and treatment of medical indications characterized by inflammation, pain, and itching. The first clinical indication under development is Epidermolysis Bullosa (EB). EB is a rare inherited disorder characterized by mechanical stress-induced blistering of the skin and mucous membranes. INM-755 is a cream containing cannabinol (CBN) as the active substance.
This study will investigate the local safety and tolerability of topically applied INM-755 on epidermal wounds of healthy volunteers. Each subject will receive four treatment options on separate epidermal wounds according to a randomized double-blind design. Treatments will be applied daily for 14 days.

Doel van het onderzoek

This study is exploratory and no formal hypothesis is set.

Onderzoeksopzet

For 22 days from first treatment till EOS

Onderzoeksproduct en/of interventie

INM-755 cream, vehicle

Contactpersonen

Publiek

Centre for Human Drug Research
R. Rissmann

+31 71 5246 400

Wetenschappelijk

Centre for Human Drug Research
R. Rissmann

+31 71 5246 400

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male or female subject between 18 and 45 years of age inclusive at the time of consent.
2. Body mass index (BMI) between 18 and 30 kg/m2, inclusive, and with a minimum weight of 50 kg.
3. Subject is in good general health, according to the investigator’s judgement based on vital signs, medical history, physical examination, and laboratory tests performed.
4. Contraception:
a. Male participants:
i. A male participant who agrees to follow the contraceptive guidance during their participation in this study from Day 1 until at least 90 days after the last treatment administration.
b. Female participants:
i. A female participant is eligible to participate if she is not pregnant, does not plan to become pregnant during the study, not breastfeeding, and at least 1 of the following conditions applies:
1. Not a women of child-bearing potential (WOCBP)
OR
2. A WOCBP who agrees to follow the contraceptive guidance during their participation in this study from at least 90 days before Day 1 until at least 90 days after the last treatment administration.
5. Female subject has had a negative urine pregnancy test at screening and at Day 1 before dosing.
6. Subject is willing to participate and is capable of giving informed consent.
7. Subjects must be willing to comply with all study procedures, have the ability to communicate well with the investigator in Dutch language and must be available for the duration of the study.
8. Subject has sufficient application area of healthy intact skin of the back (>100 cm2).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Subject is a female who is breastfeeding, pregnant, or who is planning to become pregnant during the study.
2. Subject has a history of skin disease or presence of skin condition that, in the opinion of the investigator, would interfere with the study assessments.
3. Subject has presence of or has a history of atopic dermatitis or psoriasis.

4. Any known allergy or hypersensitivity to medical adhesives used in this study or any component of the study product (e.g., Poloxamers, Lecithin, Isopropyl Palmitate).
5. Subject has a positive reaction to skin marker test and/or dermographism test.
6. Subject has presence of any tattoos, scratches, open sores, excessive hair, or skin damages in the target treatment area(s) that, in the opinion of the investigator, may interfere with study evaluations.
7. Subject has a Fitzpatrick's Skin Phototype ≥4.
8. Subject is known to have immune deficiency or is immunocompromised.
9. Subject has a known history of chronic infectious disease (e.g., hepatitis B, hepatitis C, or infection with human immunodeficiency virus).
10. Subject has a history of cancer or lymphoproliferative disease within 5 years prior to Day 1. Subjects with successfully treated nonmetastatic cutaneous squamous cell or basal cell carcinoma and/or localized carcinoma in situ of the cervix are not to be excluded.
11. Subject had a major surgery within 8 weeks prior to Day 1 or has a major surgery planned during the study.
12. Subject has any clinically significant medical condition or physical, laboratory, ECG, or vital signs abnormality that would, in the opinion of the investigator, put the subject at undue risk or interfere with interpretation of study results.
13. Subject has used any systemic treatment that could be immunosuppressive (including oral corticosteroids, oral retinoids, immunosuppressive medication, methotrexate, cyclosporine, or apremilast) within 4 weeks prior to Day 1. Note: Intranasal corticosteroids and inhaled corticosteroids are allowed. Eye and ear drops containing corticosteroids are also allowed.
14. Subject has had excessive sun exposure, is planning a trip to a sunny climate, or has used tanning booths within 4 weeks prior to Day 1 or is not willing to minimize natural and artificial sunlight exposure during the study. Use of sunscreen products (except on application areas) and protective apparel are recommended when sun exposure cannot be avoided.
15. Subject has received laser treatment, electrolysis on the application areas within 4 weeks prior to Day 1 or is planning to during the study period.
16. Subject has shaved the application area 72 hours prior to Day 1 or is planning to do so during the study period.
17. Subject has used cannabis or any cannabinoid products within 12 weeks prior to Day 1.
18. Subject has used any medication known to impair alertness and/or ability to detect discomfort within 1 week prior to Day 1.
19. Subject has used a topical applied treatment on the targeted application area(s) within 1 week prior to Day 1.
20. Subject has a known history of clinically significant drug or alcohol abuse in the last year prior to Day 1.
21. Subject has a positive screen result for drug of abuse at screening and at Day 1 before dosing.
22. Subject is unwilling to avoid contact with water on the treatment condition area(s) during the treatment period.
23. Subject is requiring frequent use of pain medication (e.g., acetaminophen or NSAIDs) to relieve chronic pain (e.g., frequent headaches, migraines, dysmenorrhea, arthritis).
24. Subject has a history of hypertrophic scarring or keloid formation in scars or suture sites.
25. Subject has taken anticoagulant medication, such as heparin, low molecular weight

(LMW)-heparin, warfarin, antiplatelets (except low-dose aspirin ≤81 mg which will be allowed), within 2 weeks prior to Day 1, or has a
contraindication to skin biopsies.
26. Loss or donation of blood over 500 mL within 12 weeks prior to screening.
27. Participation in any marketed or investigational drug or device study within 3 months or 5 half-lives (whichever is longer) prior to first dosing
28. Subject has a body temperature of >38 °C at any visit.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2020
Aantal proefpersonen:	8
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N.A.

Ethische beoordeling

Positief advies

Datum:	22-06-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49368
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8722
CCMO	NL72831.056.20
OMON	NL-OMON49368

Resultaten

Samenvatting resultaten
N.A.