A Randomized, Double-Blind, Vehicle-Controlled, Phase I Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Topically Applied INM-755 Cream in Healthy Volunteers and to Study Suction Blisters as a Wound Healing Model

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28642

Source
Nationaal Trial Register

Brief title
CHDR1930

Health condition

Healthy volunteers

Sponsors and support

Primary sponsor: InMed Pharmaceuticals Inc.
Source(s) of monetary or material Support: InMed Pharmaceuticals Inc.

Intervention

Outcome measures

Primary outcome

Evaluation of local safety and tolerability of INM-755.

Secondary outcome

Assessment of local and systemic exposure of INM-755.

Study description

Background summary

INM-755 is being developed for dermal application and treatment of medical indications characterized by inflammation and pain. The first clinical indication under development will be 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 a highly purified rare cannabinoid as the active substance. This first-on-human study will investigate the local safety and tolerability of daily topical applications for 14 days in healthy volunteers as well as the potential systemic effects, i.e., pharmacokinetics and safety.
In addition, a cutaneous suction blister will be characterized in Part 2 to use as a drug development model for epidermal wound healing in healthy volunteers. The blister wound will not be treated with INM-755. Part 2 will be conducted in parallel with Part 1 in a subset of subjects – the first 12 who agree to participate in both study parts and in whom a successful blister is created.

Study objective

This study is exploratory and no formal hypothesis is set.

Study design

Daily for 14 days, then after 1 week washout in Part 1

Intervention

INM-755 cream

Contacts

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Eligibility criteria

Inclusion criteria

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
3. Subject is in good general health, according to the investigator’s judgment 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 at least 90 days before Day 1 until at least 90 days after the last study product 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 woman 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 study product 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 the 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.

Exclusion criteria

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 (e.g., Tegaderm®) used in this study or any component of the study product (e.g., Poloxamers, Lecithin, Isopropyl Palmitate).
5. 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.
6. Subject has a Fitzpatrick's Skin Phototype ≥4.
7. Subject is known to have immune deficiency or is immunocompromised.
8. Subject has a known history of chronic infectious disease (e.g., hepatitis B, hepatitis C, or infection with human immunodeficiency virus).
9. 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.
10. Subject had a major surgery within 8 weeks prior to Day 1 or has a major surgery planned during the study.
11. 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.
12. 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.
13. 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.
14. 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.
15. Subject has shaved the application area 72 hours prior to Day 1,or is planning to do so during the study period.
16. Subject has used cannabis or any cannabinoid products within 12 weeks prior to Day 1.
17. Subject has used any medication known to impair alertness and/or ability to detect discomfort within 1 week prior to Day 1.
18. Subject has used a topical administrated treatment on the targeted application area(s) within 1 week prior to Day 1.
19. Subject has a known history of clinically significant drug or alcohol abuse in the last year

prior to Day 1.
20. Subject has a positive screen result for drug of abuse at screening and at Day 1 before dosing.
21. Subject is unwilling to avoid contact with water on the treatment condition area(s) during the treatment period.
22. Subject is requiring frequent use of pain medication (e.g., acetaminophen or NSAIDs) to relieve chronic pain (e.g., frequent headaches, migraines, dysmenorrhea, arthritis).
23. Subject has a history of hypertrophic scarring or keloid formation in scars or suture sites.
24. Subject has taken anticoagulant medication, such as heparin, low molecular weight (LMW)-heparin, warfarin, anti-platelets (except low-dose aspirin ≤81 mg which will be allowed), within 2 weeks prior to Day 1, or has a contraindication to skin biopsies.
25. Loss or donation of blood over 500 mL within 12 weeks prior to screening
26. Participation in any marketed or investigational drug or device study within 12 weeks or 5 half-lives (whichever is longer) prior to first dosing.
27. Subject has a history of an allergic reaction or significant sensitivity to lidocaine or other local anesthetics.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-12-2019
Enrollment:	22
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
N.A.

Ethics review

Positive opinion
Date: 06-01-2020
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48156
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8269
CCMO	NL71806.056.19
OMON	NL-OMON48156

Study results

Summary results
N.A.