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Can a cannabis-based medicine applied to a non-healing wound improve healing and reduce pain?

Submission date
08/03/2020

Recruitment status
No longer recruiting

Registration date
10/03/2020

Overall study status
Completed

Last Edited
19/05/2023

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Wound healing is a serious problem worldwide. Non-healing wounds lead to reduced quality of life, limb amputation, increased death rates, and losses in human productivity. They can also lead to increased opioid use (and potential addiction) and antibiotic resistance. In the USA, nearly $100 billion is spent each year on on wound-related treatments, mostly on dressings that do not treat the underlying medical problems that stop the wound healing.
Wounds that do not heal are stalled in a state of extreme inflammation. The cannabis plant contains several types of anti-inflammatory chemicals. These include cannabinoids, which have been shown to reduce inflammation and enable the wound healing process to progress, as well as flavonoids and terpenes that also have positive effects on wound healing.
This study aims to investigate a topical medicine (meaning one that is applied directly to the site of the disease) based on cannabis in wounds that have not healed for 6 months or more. The treatment will be applied to the wound and around the wound. The effects on healing and pain will be measured.

Who can participate?
Adults with non-healing, deep wounds that have not healed for at least 6 months despite treatment

What does the study involve?
Participants will apply the medicine to the wound and around the wound once a day until it has healed.

What are the possible benefits and risks of participating?
There are not thought to be any side effects from the cannabis-derived ingredients of the medicine. The medicine acts at the site of the wound and is not distributed around the body to a significant extent. However, there is a small risk that application of the medicine might introduce infection into the wound.
The potential benefits are that the medicine might stimulate wound healing or reduce pain.

Where is the study run from?
William Osler Health System (Canada)

When is the study starting and how long is it expected to run for?
May 2018 to June 2019

Who is funding the study?
VinSan Therapeutics Inc (Canada), which produces the cannabis-based medicine

Who is the main contact?
Dr Vincent Maida, vintordoc@icloud.com

Contact information

Type(s)
Public

Contact name
Dr Vincent Maida

ORCID ID
http://orcid.org/0000-0002-8693-0617

Contact details
Palliative Care Unit
9th Floor
101 Humber College Boulevard
Toronto
Canada
L4L 7B2
+1 416-346-6829
vintordoc@icloud.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Topical cannabis-based medicines for wound healing and pain management

Study objectives
Integumentary wounds are states of dysregulation within the endogenous cannabinoid system (ECS). Topical cannabis-based medicines (TCBM), composed of proprietary mixtures of cannabinoids, terpenes, and flavonoids, are postulated to interact with the multiple elements of the ECS, and other signalling systems to restore homeostasis and thus promote integumentary wound healing and relieve wound-related pain. TCBM is applied to both the wound bed and the peri-wound integument as ECS dysregulation is present in both areas.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/06/2018, William Osler Health System Research Ethics Board (Room S.3.907, 2100 Bovaird Drive East, Brampton, Ontario, L6R 3J7, Canada; +1 (905) 494-2120 x50448; Michelle.Dimas@williamoslerhs.ca), ref: 18-0038

Study design
Prospective open-label serial case series

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Included within the consent form

Health condition(s) or problem(s) studied
Intractable non-healing wounds afflicting patients with vasculitic and vasculopathic disorders

Interventions
A thin layer of VinSan was applied topically to both the wound bed and peri-wound integumentary tissues (approximately a 2-5 cm cuff around the wound bed) daily until complete wound closure.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
VinSan topical cannabis-based medicines

Primary outcome measure
Time to complete wound closure as reported by participants or family members

Secondary outcome measures
1. Wound-related pain assessed in terms of analgesic use in daily milligram morphine equivalents (MME)
2. Wound size (longest length x widest width in cm2) measured at each clinic or home visit by the investigator or their delegate

Overall study start date
28/05/2018

Completion date
06/06/2019

Eligibility

Key inclusion criteria
Intractable, non-healing integumentary wounds of more than 6 months duration that have failed best practices and evidence-based medical treatments

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
approximately 30 patients

Total final enrolment
42

Key exclusion criteria
1. Declined to sign informed consent
2. Reported a prior misadventure with cannabis
3. Allergy to cannabis

Date of first enrolment
06/06/2018

Date of final enrolment
10/05/2019

Locations

Countries of recruitment
Canada

Study participating centre
Etobicoke General Hospital
101 Humber College Boulevard
Toronto
Canada
M9V 1R8

Sponsor information

Organisation
William Osler Health System

Sponsor details
2100 Bovaird Drive East
Brampton
Canada
L6R 3J7
+1 905-494-2120
Ronald.Heslegrave@williamoslerhs.ca

Sponsor type
Hospital/treatment centre

Website
http://www.williamoslerhs.ca/

ROR
https://ror.org/03d1xjg58

Funder(s)

Funder type
Industry

Funder Name
VinSan Therapeutics Inc

Results and Publications

Publication and dissemination plan
We plan to publish a series of cohort manuscripts derived from the overall case series. We intend to submit to general medicine journals, dermatology journals, and wound management journals.

Intention to publish date
01/05/2020

Individual participant data (IPD) sharing plan
The anonymized data in Excel files is available on request from Dr Vincent Maida (vintordoc@icloud.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		17/07/2020	17/07/2020	No	No
Results article		01/09/2021	29/03/2022	Yes	No
Other files	Case study of 2 participants	02/09/2020	19/05/2023	No	No