

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

<b>Submission date</b> 08/03/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/03/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/05/2023	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> 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

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## 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 cm<sup>2</sup>) 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?
<a href="#">Basic results</a>		17/07/2020	17/07/2020	No	No
<a href="#">Results article</a>		01/09/2021	29/03/2022	Yes	No
<a href="#">Other files</a>	Case study of 2 participants	02/09/2020	19/05/2023	No	No