# Using ultrasound to evaluate white blood cell cancer in the skin

Submission date 17/11/2019	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered	
Registration date	Overall study status	Statistical analysis plan	
19/11/2019	Completed	[X] Results	
Last Edited 03/01/2023	<b>Condition category</b> Cancer	Individual participant data	

#### Plain English summary of protocol

Background and study aims

Mycosis fungoides is the most common form of a type of blood cancer called cutaneous T-cell lymphoma. Cutaneous T-cell lymphomas occur when certain white blood cells, called T cells, become cancerous; these cancers characteristically affect the skin, causing different types of skin lesions.

The diagnosis of Mycosis fungoides is often delayed since the skin lesions look similar to other skin diseases. While in many cases a diagnosis of skin diseases can be made clinically and does not require a skin biopsy, the diagnosis of Mycosis fungoides requires a skin biopsy and sometimes many skin biopsies are needed to make the correct diagnosis.

A possible new method for diagnosis is skin ultrasound, which is a fast method (done within minutes) and causes no harm or pain.

Who can participate?

Patients who have been diagnosed with Mycosis fungoides.

What does the study involve?

The study involves the application of ultrasound and dermoscopy (as non-invasive techniques) for the assessment of cutaneous lymphoma lesions.

What are the possible benefits and risks of participating? There are no direct benefits for the patients and no potential risks of participation are anticipated.

Where is the study run from? Sunnybrook Health Sciences Centre, Toronto, Canada

When is the study starting and how long is it expected to run for? December 2019 to June 2021

Who is funding the study? Investigator initiated and funded Who is the main contact? Dr Iris Wohlmuth-Wieser iris.wohlmuthwieser@sunnybrook.ca Dr Raed Alhusayen raed.alhusayen@sunnybrook.ca

## **Contact information**

**Type(s)** Scientific

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# Additional identifiers

EudraCT/CTIS number Nil known

**IRAS number** 

**ClinicalTrials.gov number** Nil known

Secondary identifying numbers 299-2019

# Study information

**Scientific Title** The implementation of novel imaging techniques for the evaluation of cutaneous lymphomas

**Acronym** ITCL

#### Study objectives

The aim of the study is to prospectively obtain high-frequency ultrasound images (HF-USG) in MF patients of different stages of the disease, in order to describe baseline HF-USG criteria for MF

and to compare the HF-USG images with dermoscopy and macroscopic images from the same index skin lesion

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved 29/10/2019, Research Ethics Board, Sunnybrook Health Sciences Centre (2075 Bayview Ave, Toronto, M4N 3M5, Ontario, Canada; +1 416-480-6100; monica.hung@sunnybrook. ca), ref: 299-2019

**Study design** Prospective single-center observational cohort study

**Primary study design** Observational

**Secondary study design** Cohort study

**Study setting(s)** Hospital

**Study type(s)** Diagnostic

**Participant information sheet** No participant information sheet available

#### Health condition(s) or problem(s) studied

Mycosis fungoides (cutaneous lymphoma)

#### Interventions

The study is designed to investigate the applicability of HF-USG in patients with mycosis fungoides using Vevo MD®; FUJIFILM VisualSonics, Toronto, ON, Canada ultrasound machine and to describe baseline ultrasound charateristics for mycosis fungoides and to compare these findings with standard dermoscopy.

Non-invasive standard dermoscopy and ultrasound images will be obtained from an index lesion of the patient. The patient will remain under standard of care. There will be no additional biopsies obtained for study purposes. The investigators will only take non-invasive images as described above, thus not imposing any potential harm to the patient. The total duration of the observation is expected to take 30 minutes (one single visit). No follow-up visits are planned for this study.

#### Intervention Type

Device

**Phase** Not Applicable

#### Drug/device/biological/vaccine name(s)

Vevo MD® ultrasound machine

#### Primary outcome measure

Ultrasound characteristics (morphology of the epidermis, dermis and subcutis) for mycosis fungoides measured using the Vevo MD® ultrasound machine at the time of investigation

#### Secondary outcome measures

Dermoscopy characteristics (pattern of the skin lesion including the morphology of vessels, follicular openings and the color of scales) for mycosis fungoides measured using skin surface microspcopy at the time of investigation

**Overall study start date** 01/11/2019

**Completion date** 30/06/2021

# Eligibility

**Key inclusion criteria** Patch or plaque stage mycosis fungoides

Participant type(s) Patient

**Age group** All

**Sex** Both

**Target number of participants** 30

**Total final enrolment** 30

#### Key exclusion criteria

Clinical suspicion of mycosis fungoides lacking definitive histopathologic proof
Mycosis fungoides with generalized erythroderma

Date of first enrolment 01/12/2019

Date of final enrolment 30/06/2021

## Locations

**Countries of recruitment** Canada

Study participating centre Sunnybrook Health Sciences Centre 2075 Bayview Avenue Toronto, ON Canada M4N 3M5

## Sponsor information

**Organisation** Sunnybrook Health Sciences Centre

Sponsor details 2075 Bayview Ave Toronto Canada M4N 3M5 +1 416 480 4908 lyn.sarceda@sunnybrook.ca

**Sponsor type** Hospital/treatment centre

Website https://sunnybrook.ca

ROR https://ror.org/03wefcv03

## Funder(s)

**Funder type** Other

**Funder Name** Investigator initiated and funded

# **Results and Publications**

#### Publication and dissemination plan

We plan to publish our data in a pubmed-listed journal.

The study protocol is available on request from the study contacts.

## Intention to publish date

01/08/2021

#### Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

#### IPD sharing plan summary

Available on request

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>		23/12/2020	03/01/2023	Yes	No