ISRCTN14038061 https://doi.org/10.1186/ISRCTN14038061

Using ultrasound to evaluate white blood cell cancer in the skin

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

Plain English Summary

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

Contact name
Dr Iris Wohlmuth-Wieser

ORCID ID
http://orcid.org/0000-0003-4714-838X

Contact details
2075 Bayview Ave
Toronto
Canada
M4N 3M5
+1 416 4804908
iris.wohlmuthwieser@sunnybrook.ca

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 hypothesis
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

Condition
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

Overall study end date
30/06/2021

Eligibility

Participant 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

Participant exclusion criteria
1. Clinical suspicion of mycosis fungoides lacking definitive histopathologic proof
2. Mycosis fungoides with generalized erythroderma

Recruitment start date
01/12/2019

Recruitment end date
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?
Results article		23/12/2020	03/01/2023	Yes	No