

Photoacoustic and ultrasound lung scanning for evaluation of lung injury

Submission date 02/09/2026	Recruitment status Recruiting	☒ Prospectively registered ☒ Protocol
Registration date 04/09/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 04/09/2026	Condition category Respiratory	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Pulmonary edema is fluid buildup in the lungs, while pulmonary fibrosis is lung scarring. These conditions can sometimes look similar on standard imaging despite requiring different treatments. PULSE-LI is testing two research imaging methods, quantitative ultrasound and photoacoustic imaging, to develop imaging biomarkers that may help distinguish pulmonary edema from pulmonary fibrosis.

Who can participate?

Adult patients with acute decompensated heart failure and moderate-to-severe pulmonary edema, patients with idiopathic pulmonary fibrosis with a definite usual interstitial pneumonia pattern on computed tomography, and healthy volunteers.

What does the study involve?

Healthy volunteers will attend one imaging visit to help optimize the scanning protocol. Patients will attend one research imaging session using quantitative ultrasound and photoacoustic imaging. Researchers will also collect relevant demographic and clinical information. Patients may separately consent to an optional blood test for N-terminal pro-B-type natriuretic peptide. The research imaging results will not be used for diagnosis or treatment decisions.

What are the possible benefits and risks of participating?

Participants are not expected to receive a direct medical benefit. The study may help develop better bedside imaging methods for lung disease in the future. Risks are expected to be low and may include temporary discomfort from the probe, gel, positioning or protective eyewear. Photoacoustic imaging uses laser light, so protective eyewear is required. Optional blood sampling may cause brief pain, bruising or light-headedness.

Where is the study run from?

St. Michael's Hospital, Unity Health Toronto, Toronto, Ontario, Canada.

When is the study starting and how long is it expected to run for?

September 2026 to September 2027

Who is funding the study?

The study is investigator-sponsored and supported by the St. Michael's Hospital Medical Services Association Academic Health Science Centre Alternative Funding Plan Innovation Fund Award.

Who is the main contact?

Dr Alberto Goffi, St. Michael's Hospital, Unity Health Toronto, alberto.goffi@unityhealth.to.

Contact information

Type(s)

Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title

Photoacoustic and ultrasound lung scanning for evaluation of lung injury (PULSE-LI): a prospective observational study of healthy adults, adults with acute decompensated heart failure-associated pulmonary edema, and adults with idiopathic pulmonary fibrosis, using quantitative ultrasound and photoacoustic imaging to develop and preliminarily validate structural and functional imaging biomarkers that differentiate pulmonary edema from pulmonary fibrosis

Acronym

PULSE-LI

Study objectives

Primary Objective:

Develop and preliminarily validate QUS- and PAI/MSOT-derived investigational imaging biomarkers capable of differentiating pulmonary edema from pulmonary fibrosis at the bedside.

Secondary Objectives:

1. Assess biomarker reproducibility
2. Evaluate the impact of participant characteristics (e.g., skin tone, sex) on imaging performance

3. Explore associations between investigational imaging biomarkers and physiologic, laboratory, and standard imaging parameters

Ethics approval required

Ethics approval required

Ethics approval(s)

Submitted 02/09/2026, Unity Health Toronto Research Ethics Board (St. Michael's Hospital 30 Bond St, Toronto, M5B 1W8, Canada; +1 416 864 6060 ext. 42557; researchethics@unityhealth.to), ref: 25-131

Primary study design

Observational

Secondary study design

Cohort study

Study type(s)

Health condition(s) or problem(s) studied

Development and validation of novel imaging biomarkers derived from quantitative ultrasound (QUS) and photoacoustic imaging (PAI) to differentiate between pulmonary edema and pulmonary fibrosis.

Interventions

This is a prospective, single-centre observational imaging study conducted in two sequential phases. Participants are not randomized and no treatment is assigned. Participants are enrolled into one of three groups according to their clinical status: healthy adults, adults hospitalized with acute decompensated heart failure and moderate-to-severe pulmonary edema, and adults with idiopathic pulmonary fibrosis and a definite usual interstitial pneumonia pattern on high-resolution computed tomography.

In Phase 1, 20 healthy adult volunteers will undergo one research imaging session using quantitative ultrasound and photoacoustic imaging. The thorax will be scanned in protocol-defined anterior, lateral and posterior regions using longitudinal and transverse probe orientations. Quantitative ultrasound images and raw ultrasound radiofrequency data will be acquired, followed by photoacoustic imaging of corresponding thoracic regions. Probe position may be marked on the skin to facilitate spatial alignment between the two imaging techniques. Different acquisition conditions, including tidal breathing versus breath-holding, timing within the respiratory cycle, probe position and insonation angle, will be evaluated to optimize the imaging protocol. Inter- and intra-operator reproducibility will also be assessed. The healthy-volunteer study visit is expected to last no more than 80 minutes, with quantitative ultrasound and photoacoustic scanning each lasting no more than approximately 30 minutes.

In Phase 2, 30 patients will be enrolled: 15 with acute decompensated heart failure and moderate-to-severe pulmonary edema and 15 with idiopathic pulmonary fibrosis with a definite usual interstitial pneumonia pattern on high-resolution computed tomography. Each participant will undergo one research imaging session using the quantitative ultrasound and photoacoustic imaging protocol developed in Phase 1. The patient imaging session is expected to last no more

than 30 minutes, with approximately 5 minutes of quantitative ultrasound scanning and 5 minutes of photoacoustic imaging. Skin markings may be used to align imaging locations between the two techniques and, where applicable, with computed tomography images.

Quantitative ultrasound data will be analysed to develop structural imaging biomarkers related to lung tissue scatterer concentration, size and spacing. Photoacoustic imaging data will be analysed to develop functional and molecular imaging biomarkers related to total haemoglobin concentration/perfusion, oxygen saturation, and water and collagen content. These biomarkers will be compared between healthy, edematous and fibrotic lungs and evaluated for their ability to differentiate pulmonary edema from pulmonary fibrosis.

Demographic information including age, sex, weight, height and skin tone will be collected. For patient participants, relevant clinical information will also be obtained from assessments and medical records, including comorbidities, dyspnea and functional classification, pulmonary function tests, six-minute walk testing, chest computed tomography and chest radiography, laboratory investigations, echocardiography, oxygen requirements, oxygen saturation, respiratory rate, blood pressure, heart rate and, where available, arterial blood gas measurements.

Patient participants may separately consent to an optional same-day blood sample for N-terminal pro-B-type natriuretic peptide measurement. For hospitalized participants with acute decompensated heart failure, this test will be added to clinically indicated bloodwork whenever feasible to avoid an additional venipuncture. For outpatients with idiopathic pulmonary fibrosis, one study-specific blood sample will be collected at the beginning of the imaging visit. Healthy volunteers will not undergo blood sampling as part of the study.

All quantitative ultrasound and photoacoustic imaging measurements are investigational and are collected for research purposes only. They will not be used for clinical diagnosis, monitoring or treatment decisions, and participants will continue to receive their usual clinical care independently of the study imaging results.

Intervention Type

Device

Phase

Phase II/III

Drug/device/biological/vaccine name(s)

TUPIL MSOT Acuity Echo

Primary outcome(s)

1. Discrimination between pulmonary edema and pulmonary fibrosis measured using the area under the receiver-operating characteristic curve of a combined classifier derived from quantitative ultrasound structural biomarkers and photoacoustic imaging functional biomarkers at Day 0 (single study imaging visit)

Key secondary outcome(s)

1. Inter-operator reproducibility of quantitative ultrasound and photoacoustic imaging biomarkers measured using intraclass correlation coefficient calculated from biomarker measurements obtained by two operators at Day 0 (single study imaging visit)

2. Intra-operator reproducibility of quantitative ultrasound and photoacoustic imaging biomarkers measured using intraclass correlation coefficient calculated from repeated biomarker measurements obtained by the same operator at Day 0 (single study imaging visit)
3. Association between skin tone and quantitative ultrasound and photoacoustic imaging biomarkers measured using an association between biomarker measurements and skin tone assessed using the Monk Skin Tone Scale at Day 0 (single study imaging visit)
4. Association between investigational imaging biomarkers and clinical and physiological measurements measured using the correlation of quantitative ultrasound and photoacoustic imaging biomarkers with available clinical and physiological measurements, including oxygenation, N-terminal pro-B-type natriuretic peptide concentration and pulmonary function measurements, using Spearman correlation coefficients at Day 0 (single study imaging visit)
5. Differences in quantitative ultrasound and photoacoustic imaging biomarkers among healthy, pulmonary edema and pulmonary fibrosis groups measured using a comparison of biomarker distributions among the three participant groups using analysis of variance or the Kruskal-Wallis test, as appropriate at Day 0 (single study imaging visit)

Completion date

15/09/2027

Eligibility

Key inclusion criteria

Pulmonary Edema Cohort:

Patients hospitalized with acute decompensated heart failure (ADHF) with moderate-to-severe pulmonary edema

Pulmonary Fibrosis Cohort:

Patients with a diagnosis of IPF with a definite usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT), undergoing outpatient follow-up in pulmonology clinics

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

18 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

Healthy Volunteers

1. Unable or unwilling to provide informed consent
2. Active smoker, defined as current cigarette smoking or smoking within the past 30 days
3. History of lung or cardiac diseases
4. Tattoos or exogenous pigments within the field of view
5. Pregnancy
6. Photosensitizing medication within 72 hours (e.g., sulfonamides, ampicillin, tetracycline)
7. Current phototherapy
8. History of photosensitive disease, such as porphyria or lupus erythematosus, treatment for a photosensitive disease, or active clinically relevant photosensitivity
9. Open skin lesions/sensitivity in scan field
10. Inability/unwillingness to wear laser safety eyewear
11. Recent use of gas ultrasound contrast agent
12. Inability to tolerate positioning/probe pressure

Patients

1. Unable or unwilling to provide informed consent
2. Inability to cooperate with the ultrasound examination (e.g. severe agitation, altered mental status)
3. Invasive mechanical ventilation or non-invasive mechanical ventilation at the time of the study procedure
4. Chronic obstructive pulmonary disease (COPD)
5. Lung emphysema
6. Active malignancy with lung involvement
7. End-stage renal disease requiring renal replacement therapy
8. Recent or active lung infection
9. Acute respiratory distress syndrome (ARDS)
10. Recent thoracic surgery or trauma
11. Active tuberculosis
12. Known history of granulomatous lung disease
13. Active smoking, defined as current cigarette smoking or smoking within the past 30 days
14. Tattoos or exogenous pigments within the field of view
15. Pregnancy
16. Photosensitizing medication within 72 hours (e.g., sulfonamides, ampicillin, tetracycline)
17. Current phototherapy
18. History of photosensitive disease, such as porphyria or lupus erythematosus, treatment for a photosensitive disease, or active clinically relevant photosensitivity
19. Open skin lesions/sensitivity in scan field
20. Inability/unwillingness to wear laser safety eyewear
21. Recent use of gas ultrasound contrast agent
22. Inability to tolerate positioning/probe pressure

Date of first enrolment

15/09/2026

Date of final enrolment

15/06/2027

Locations

Countries of recruitment

Canada

Study participating centre

St. Michael's Hospital

30 Bond Street

Toronto

Canada

M5B 1W8

Sponsor information

Organisation

St. Michael's Hospital

ROR

<https://ror.org/04skqfp25>

Funder(s)

Funder type

Funder Name

St. Michael's Hospital Medical Services Association (SMHA) AHSC AFP Innovation Fund Award.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.1	17/08/2026	04/09/2026	No	No