

Multi-site Study of the Clinical Impact of an AI-assisted Approach to Referring Patients With Interstitial Lung Disease for Diagnostic Evaluation of Pulmonary Hypertension

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* 18 years or older at the time of consent * A known diagnosis of interstitial lung disease * Diffusing capacity for carbon monoxide (DLCO) $\leq$ 30% predicted, collected within 6 months prior to consent * Willing and able to provide informed consent and undergo all study-specific procedures, including echo and RHC, if required

Exclusion Criteria:

* A known diagnosis of pulmonary hypertension (including patients prescribed a therapy specifically for pulmonary arterial hypertension (PAH)) * A RHC was completed within the previous 1 year or ordered and not yet completed at the time of consent * LV ejection fraction $\leq$ 40% on most recent echo or cardiac MRI, if available * Unclassifiable Tempus PH ECG risk result after up to 2 ECG acquisitions * A contraindication to RHC exists (for example, pregnancy or mechanical right heart valve) * Physician decision that if a patient is directed to RHC by the study protocol, the potential risks of RHC outweigh the potential benefits * There is a severe concomitant illness limiting life expectancy to less than 6 months (at the discretion of the investigator) * There is a medical or social factor that makes the patient a poor candidate for the study and/or unlikely to be able to comply with the study protocol or complete study procedures (at the discretion of the investigator)

Conditions & Interventions

Interventions:

DEVICE: ECG-based AI Device - Results Returned to Investigator, PROCEDURE: Echocardiogram and Right Heart Catheterization, DEVICE: ECG-based AI Device - Results Not Returned to Investigator

Conditions:

Pulmonary Hypertension, Interstitial Lung Disease (ILD)

Keywords:

Pulmonary Hypertension, Interstitial lung disease (ILD)

More Information

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Principal Investigator:

IRB

Number:

System ID: NCT06911632

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