A-mode ultrasound measurement of jugular venous pulse wave versus invasive hemodynamics: a comparison between pulmonary hypertension and healthy controls, and hemodynamic modulation (LUMINA-study)

Published: 23-04-2025
Last updated: 02-05-2025

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON57438

Source
ToetsingOnline

Brief title
Sonographic JVPW vs. invasive hemodynamics in PH

Condition

- Other condition
- Heart failures

Synonym
pulmonary hypertension; high blood pressure in the lungs

Health condition

Pulmonale arteriële hypertensie

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Hemodynamics, Jugular Venous Pulse, Pulmonary Arterial Hypertension, Right Ventricular Dysfunction

Outcome measures

Primary outcome

The full sonographic JVPW at rest will be compared between patients and healthy controls. Invasive measurement of right ventricular end-diastolic pressure (RVEDP) through RHC will be analyzed to determine whether RVEDP can be predicted using JVPW characteristics.

Secondary outcome

JVPW assessments in patients after intravenous saline. Invasive hemodynamic parameters using RHC.

Study description

Background summary

Pulmonary arterial hypertension (PAH) is a progressive disease characterized by high mortality and significant complications, particularly right ventricular (RV) failure characterized by diastolic dysfunction and elevated ventricular filling pressures. Traditional assessment through right heart catheterization (RHC) is invasive and has other limitations, prompting a need for non-invasive

risk stratification methods. This study proposes sonographic assessment of the jugular venous pulse wave (JVPW) as non-invasive alternative, leveraging the internal jugular vein as an indicator of right atrial pressure. Prior research indicates correlations between jugular vein metrics and hemodynamic parameters, but no studies have yet linked JVPW to invasive measures in PAH patients. The study hypothesizes that JVPW characteristics will differ between suspected PH patients and healthy controls and that JVPW characteristics respond to (changes in) invasive cardiopulmonary hemodynamics, specifically RV filling pressures.

Study objective

This study aims to evaluate A-mode ultrasound for assessing JVPW characteristics as a non-invasive tool to discriminate between healthy subjects and those with pulmonary arterial hypertension patients, and to assess if JVPW changes relate to changes in RV filling pressures in response to intravenous saline.

Study design

This open-label, cross-sectional observational study with a single-arm intervention will compare patients with suspected PH (all world health organization (WHO) groups) (n=15) to age- and sex-matched healthy controls (n=15). Participants will be recruited through referrals and snowball sampling. Patients will receive right heart catheterization as part of routine clinical care, during which they will undergo A-mode sonographic measurements of the JVPW at rest, and after IV saline infusion to mimic worsening PAH. Invasive hemodynamic data will be recorded during both JVPW assessments. Controls will only receive A-mode sonographic JVPW measurements.

Study burden and risks

Participation in this study poses very low additional risk for the patient group, as the RHC is part of standard clinical care. The control group faces negligible risk, as they will only undergo non-invasive assessment; overall, both groups are well-protected through established clinical protocols and careful participant selection.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Age 18 years or older
- Referred for RHC without vasoreactivity assessment (i.e., RHC without Flolan procedure) at Radboudumc, due to suspected pulmonary hypertension (all world health organization (WHO) groups)
- Able to perform the informed consent procedure

Exclusion criteria

A subject who meets any of the following criteria will be excluded from participation in this study:
- Any contraindication for IV saline (i.e., decompensated heart failure; severe peripheral oedema; severe liver disease; hypernatremia; renal function of eGFR<30)
- Unable to receive ultrasound assessment of the right IJV (i.e., significant/untreated neck wounds or other dermatological conditions)
- Pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2024
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-04-2025
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL87880.091.24