

Detection of chronic thromboembolic pulmonary hypertension (CTEPH) following pulmonary embolism

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
12/05/2009	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
29/06/2009	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
08/05/2019	Circulatory System	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr John-David Aubert

Contact details

University Hospital Lausanne
Rue du Bugnon
Lausanne
Switzerland
1011

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Multicentre observational screenINg survey for the detection of chronic thromboembolic PULmonary hyperTensiON (CTEPH) following Pulmonary Embolism

Acronym

INPUT ON PE

Study objectives

1. To evaluate the incidence rate of symptomatic chronic thromboembolic pulmonary hypertension (CTEPH) following pulmonary embolism (PE)
2. To identify and evaluate potential risk factors for developing CTEPH following PE
3. To test the usefulness of a screening algorithm based on dyspnoea in medical practice for diagnosing CTEPH after confirmed PE

Ethics approval required

Old ethics approval format

Ethics approval(s)

Commission d'éthique de la recherche Lausanne approved on the 17th February 2009 (ref: 226/08)

Study design

Prospective multicentre observational phase V study

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Pulmonary embolism/chronic thromboembolic pulmonary hypertension

Interventions

Patients with confirmed pulmonary embolism are followed up by regular telephone contacts at 6, 12 and 24 months using a standardised dyspnoea questionnaire. If the questionnaire discovers previously unreported symptoms of dyspnoea, patients are invited to the centre for confirmation of dyspnoea and, if confirmed, an echocardiography will be performed.

In case of a suspicion of PH at echocardiography, right heart catheterisation is performed for the confirmation of PH. CTEPH is confirmed if mean pulmonary arterial pressure (mPAP) greater than or equal to 25 mmHg, pulmonary capillary wedge pressure (PCWP) less than 15 mmHg and pulmonary vascular resistance (PVR) greater than or equal to 300 dyn*sec/cm⁵ (3.75 Wood units), and additionally if V/Q scan shows a mismatch or imaging of the lung vessels show a pulmonary vessel obstruction. Any other causes of dyspnoea or elevated PH have to be excluded.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Amount of patients who develop symptomatic CTEPH at 6, 12 and 24 months after PE.

Key secondary outcome(s)

1. Comparison of collected baseline data of the patients who developed CTEPH with the baseline data of the patients who did not develop CTEPH within the 2-year period after diagnosis of PE to identify any potential risk factors
2. Comparison of the results of the dyspnoea questionnaire answered by telephone with the dyspnoea evaluation by the investigator at the clinic to test the usefulness of the telephone screening algorithm in medical practice for diagnosing CTEPH after PE

Completion date

01/04/2013

Eligibility

Key inclusion criteria

Men and women (no age limitations) with pulmonary embolism within the preceding 4 weeks, demonstrated by:

1. Pulmonary angiography, or
2. Contrast enhanced spiral computed tomography, or
3. High probability lung scintigraphy (perfusion and ventilation imaging)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

508

Key exclusion criteria

1. Confirmed diagnosis of pulmonary arterial hypertension (PAH) or CTEPH before inclusion
2. Pre-existing severe chronic dyspnoea (New York Heart Association [NYHA] grade III or IV) due to other reasons than PE
3. Cancer or other life-threatening disease with a life expectancy less than 6 months

Date of first enrolment

18/05/2009

Date of final enrolment

01/04/2013

Locations

Countries of recruitment

Switzerland

Study participating centre
University Hospital Lausanne
Lausanne
Switzerland
1011

Sponsor information

Organisation

Swiss Society for Pulmonary Hypertension (Switzerland)

ROR

<https://ror.org/05yp06a73>

Funder(s)

Funder type

Research organisation

Funder Name

Swiss Society for Pulmonary Hypertension (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/04/2018	08/05/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes