

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

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

**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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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'ethique 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

## Secondary study design

Single-centre

## Study setting(s)

Hospital

## Study type(s)

Screening

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## 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/cm<sup>5</sup> (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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

18/05/2009

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

1000

**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)

**Sponsor details**

c/o IMK Institut für Medizin und Kommunikation AG

Münsterberg 1

Basel

Switzerland

4001

**Sponsor type**

Research organisation

**Website**

<http://www.sgph.ch/WebHome>

ROR

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

## Funder(s)

### Funder type

Research organisation

### Funder Name

Swiss Society for Pulmonary Hypertension (Switzerland)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### 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?
<a href="#">Results article</a>	results	04/04/2018	08/05/2019	Yes	No