ISRCTN61417303 https://doi.org/10.1186/ISRCTN61417303

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

Submission date 12/05/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/06/2009	**Overall study status** Completed	
Last Edited 08/05/2019	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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^5 (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?
Results article	results	04/04/2018	08/05/2019	Yes	No