

# Pulmonary embolism diagnosis study

<b>Submission date</b> 26/09/2005	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/04/2008	<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 David Robert Anderson

**Contact details**  
Queen Elizabeth II Health Science Centre  
VGH Site, Room 430  
Bethune Building  
1278 Tower Road  
Halifax  
Canada  
B3H 2Y9  
+1 902 473 8562  
david.anderson@dal.ca

## Additional identifiers

**Protocol serial number**  
MCT-44150

## Study information

**Scientific Title**

**Study objectives**

We hypothesise that relying on the use of spiral Computed Tomography (CT) as opposed to V/Q scanning as the initial pulmonary imaging procedure to exclude the diagnosis of PE will result in similar rates of subsequent venous thromboembolic events and will be cost-effective.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval received from the Queen Elizabeth II Health Sciences Centre Research Ethics Committee on the 8th March 2001.

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Pulmonary embolism (PE)

### **Interventions**

Clinical model to identify PE likely or unlikely, Ddimer blood test, randomised to receive either V/Q or CT for diagnosis of possible PE, in majority of cases would have ultrasound to rule out deep vein thrombosis.

Trial details received: 12 September 2005

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

Symptomatic venous thromboembolism.

### **Key secondary outcome(s)**

1. Asymptomatic venous thromboembolism
2. Death
3. Bleed (major and minor)

### **Completion date**

31/07/2006

## **Eligibility**

### **Key inclusion criteria**

Consecutive adult patients (18 years and older) of either sex, presenting with symptoms or signs suspected by a physician of being caused by acute pulmonary embolism (acute onset of new or worsening shortness of breath, chest pain, hemoptysis, presyncope or syncope) will be potentially eligible for this study.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Deep vein thrombosis or pulmonary embolism within the previous 3 months
2. No worsening of the severity of pulmonary symptoms within the previous 2 weeks
3. Use of therapeutic doses of parenteral anticoagulants for greater than 48 hours
4. Co-morbid condition making life expectancy less than 3 months
5. Contradiction to contrast media
6. A need for long-term use of anticoagulants
7. Pregnancy
8. Age less than 18 years
9. Refusal to give informed consent
10. Geographic inaccessibility to follow-up

**Date of first enrolment**

01/11/2005

**Date of final enrolment**

31/07/2006

**Locations****Countries of recruitment**

Canada

**Study participating centre**

Queen Elizabeth II Health Science Centre

Halifax

Canada

B3H 2Y9

# Sponsor information

## Organisation

Queen Elizabeth II Health Science Centre (Nova Scotia) (Canada)

## ROR

<https://ror.org/025qrzc85>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-44150)

# 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?
<a href="#">Results article</a>	Results	19/12/2007		Yes	No