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Influence of active awareness about venous thromboembolism relevance and rate of symptomatic deep vein thrombosis

Submission date	Recruitment status	[_] Prospectively registered
12/01/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/01/2012	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/05/2017	Circulatory System	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Deep vein thrombosis (DVT) is a blood clot that develops within a deep vein in the body, usually in the leg, causing cause pain and swelling. The symptoms of DVT are not specific - patients can have large clots but only minimal symptoms which, if disregarded, can result in dangerous consequences including sudden death. However, most DVT patients have a good outcome. An increase in public awareness of DVT and its symptoms may in time reduce the overall disease burden. Although there have been many attempts to raise public awareness about DVT, their effects are not known. The aim of this study is to find out whether an increase in public awareness results in more people being correctly diagnosed with DVT.

Who can participate?
Patients aged over 18 with symptoms suggesting DVT

What does the study involve?
A campaign to raise public awareness of DVT is conducted in an urban area, with brochures being distributed four times during a year and posters and newsletter articles being published. This area is compared with another area that is not exposed to the campaign. Patients with symptoms of DVT in both areas are referred by their GPs for an ultrasound scan of their leg at no charge to the patient. The impact of the educational campaign on the number of patients correctly diagnosed DVT is assessed.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Institute of Tuberculosis and Lung Diseases (Instytut Gruzlicy i Chorob Pluc) (Poland)

When is the study starting and how long is it expected to run for?
December 2007 to November 2009

Who is funding the study?
Sanofi-Aventis (Poland)

Who is the main contact?
Prof. Witold Tomkowski

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DIREG L 03049

Study information

Scientific Title
Influence of Active awareness about Venous ThromboEmbolism relevance and Rate of Symptomatic deep vein thrombosis: an observational study

Acronym
AVTERS

Study objectives
An increase in public awareness would result in an increase in the frequency of objectively confirmed deep vein thrombosis (DVT), wherever its anatomic location.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Bioethics Committee, National TB and Lung Diseases Research Institute, Warsaw, Poland, 19/11/2007, ref: KE-142/2007

Study design
Multicenter observational study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
GP practice

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Deep vein thrombosis (DVT)

Interventions
A campaign to raise public awareness of DVT was conducted in an urban population cluster (A) of approximately 100,000 via distribution of brochures four times during a year and publishing posters and newsletter articles.

A comparison urban population cluster (B) of approximately 1,574,000, was not exposed to this campaign.

Patients symptomatic for DVT in both populations were referred by general practitioners for a standardized compression ultrasound (CUS) of the whole leg at no charge to the patient. Reports of positive CUS exams documented by photographs were analyzed by an independent adjudication committee blinded to the population cluster. Cluster A was followed for 8 months after the information campaign ended.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Evaluation of the impact of an educational campaign dedicated to thromboembolic complications on increased number of correctly diagnosed DVT

Secondary outcome measures

1. Evaluation of the rate of correctly diagnosed DVT among the general population in Poland
2. Evaluation of the risk factors in patients with confirmed DVT
3. Evaluation of which diagnostic methods are applied to confirm DVT symptoms

Overall study start date
01/12/2007

Completion date
30/11/2009

Eligibility

Key inclusion criteria
1. Male or female aged > 18
2. A patient with clinical symptoms suggesting thrombosis, referred by primary care physicians selected to the study
3. A patient with deep vein thrombosis confirmed with diagnostic methods
4. A patient with newly diagnosed deep vein thrombosis or with recurring thrombosis in a vein with existing thrombosis process

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
3000

Key exclusion criteria
1. Aged under 18
2. No signs or symptoms of deep vein thrombosis
3. No consent for participation in the study

Date of first enrolment
01/12/2007

Date of final enrolment
30/11/2009

Locations

Countries of recruitment
Poland

Study participating centre
Instytut Gruzlicy i Chorob Pluc
Warsaw
Poland
01-138

Sponsor information

Organisation
Sanofi-Aventis (Poland)

Sponsor details
Bonifraterska Str. 17
Warsaw
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00-203

Sponsor type
Industry

Website
http://www.sanofi-aventis.pl/

Funder(s)

Funder type
Industry

Funder Name
Sanofi-Aventis (Poland)

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