Diagnosing Pulmonary Embolism in the Context of Common Alternative Diagnoses in primary care

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Embolism and thrombosis
Study type	Observational invasive

Summary

ID

NL-OMON52757

Source
ToetsingOnline

Brief title
PECAN study

Condition

- Embolism and thrombosis

Synonym
bloodclot in pulmonary artery, Pulmonary embolism

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Clinical decision rule, Primairy care, Pulmonary embolism, YEARS strategy

Outcome measures

Primary outcome

The primary outcomes of this study will be both the proportion false negatives (i.e. the proportion of missed PE cases with a negative YEARS-strategy) and the efficiency of the strategy (i.e. the total number of patients with a negative YEARS-strategy as a proportion of all suspected cases) in primary care.

Secondary outcome

The secondary endpoints are the alternative diagnosis besides PE after 3 months of follow-up, with most importantly pneumonia. With this endpoint and the information obtained from the POC-assay for CRP, we will quantify the diagnostic value of CRP by multivariable logistic regression analyses. Besides, factors associated with a positive score on the subjective YEARS-item *PE most likely* will be identified.

Study description

Background summary

Clinical decision rules (CDRs) and D-dimer testing are available for general practitioners (GPs) to distinguish pulmonary embolism (PE) from common alternative cardiopulmonary diagnoses in patients with shortness of breath. However, D-dimer testing is often falsely elevated, leading to unneeded, costly and potential harmful referrals for CT pulmonary angiography (CTPA). To alleviate this problem, a risk-tailored diagnostic approach was recently tested and validated with good results in secondary care: the YEARS-strategy. In this strategy, the physician scores three clinical items: (i) haemoptysis, (ii) clinical signs suggestive of deep venous thrombosis, and (iii) PE considered most likely diagnosis by the physician. If none of these items is present, a

D-dimer threshold of 1000 mcg/L is applied, while if one or more items are present, the *classical* threshold of 500 mcg/L is used. If a suspected patient is below either D-dimer threshold, PE is safely ruled out (i.e. a negative YEARS-strategy and thus no recommendation for referral for CTPA). In secondary care, this algorithm leads to an absolute reduction of 14% of CTPA*s with a completely similar safety (only 0.4% missed PE cases), as compared to a fixed D-dimer threshold of 500 mcg/L. Currently, this approach is therefore considered standard-of-care in order to rule-out PE on emergency wards in the Netherlands. This strategy however is not yet implemented in primary care, and awaits validation in this healthcare setting.

Study objective

Our primary objective is to prospectively implement and validate the YEARS strategy in primary care. Secondary objectives are, (i) to quantify the added diagnostic value of C-reactive protein (CRP) to a clinical assessment and D-dimer testing in order to enhance distinguishing PE from a pneumonia, (ii) to develop a polytomous logistic model for estimating the diagnostic probability of both PE and, and (iii) to statistically quantify predictors for assessing PE as most likely diagnosis by GPs.

Study design

Prospective diagnostic cohort study.

Study burden and risks

Using a clinical decision rule, D-dimer testing and subsequently decide on the appropriate referral decisions depending on those outcomes, is worldwide routine clinical practice and based upon current (inter)national guidelines. The YEARS-strategy is a variation (or updating) of such a decision model guided diagnostic strategy. Accordingly, there is not a true related harm to participating in this study for validation of this YEARS strategy. In addition, a novel aspect of this study is the additional point of care (POC) CRP testing simultaneously with D-dimer testing. An important advantage of this POC test, is the ability of the GP to better and earlier discriminate between the presence of PE or the most common alternative diagnosis (namely pneumonia) and thus manage PE suspected patients more accurately. Previous research showed that the YEARS strategy is safe in a secondary care setting with 14% fewer referrals for CTPA and consequently applying the YEARS-strategy is now standard-of-care in (many) emergency wards in the Netherlands (including the UMC Utrecht). Alongside patient accrual into the study, we will evaluate study findings (notably the implementation safety), on a regular basis using pre-specified stopping rules (see chapter 9). Furthermore, a decrease of CTPA*s will lead to less exposure to radiation, potential allergic reactions to contrast material, contrast-induced nephropathy and healthcare costs. Finally,

a decrease of referrals to secondary care results in less burden and insecurity in those patients. Both can be considered as benefits for participating into this study.

Contacts

Public
Universitair Medisch Centrum Utrecht

Universiteitsweg 100
Utrecht 3584 CG
NL
Scientific
Universitair Medisch Centrum Utrecht

Universiteitsweg 100
Utrecht 3584 CG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Subacute new onset or worsening of existing shortness of breath with or without chest symptoms, in whom the general practitioner first wants to exclude pulmonary embolism (PE);
- Age >= 18 years.

Exclusion criteria

- Pregnancy;
- Already using anticoagulants (i.e. a vitamin K antagonist, low-molecular weight heparine or a direct oral anticoagulant);
- Life expectancy < 1 month.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2018
Enrollment:	750
Type:	Actual

Ethics review

Approved WMO Date:	01-08-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	06-12-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-03-2019

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-08-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-11-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-02-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-07-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-02-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	08-07-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	22-06-2022
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20006
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64357.041.18
OMON	NL-OMON20006