Diagnosing pulmonary embolism in the context of common alternative diagnoses in primary care

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20006

Bron
Nationaal Trial Register

Verkorte titel
PECAN

Aandoening

Pulmonary embolism, clinical decision rule, YEARS strategy, primary care / Longembolie, beslisregel, YEARS strategie, eerstelijnszorg

Ondersteuning

Primaire sponsor: Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht (UMCU)
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcomes of this study will be both the safety and efficiency of the YEARS-strategy in primary care.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Clinical decision rules and D-dimer testing are available for general practitioners to distinguish pulmonary embolism (PE) from common alternative cardiopulmonary diagnoses in patients with a suspicion of PE. 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 secondary care, this algorithm leads to an absolute reduction of 14% of CTPAs with a completely similar safety (only 0.4% missed PE cases), as compared to a fixed D-dimer threshold of 500 mcg/L. This strategy however is not yet implemented in primary care, and awaits validation in this healthcare setting.

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 pneumonia, and (iii) to statistically quantify predictors for assessing PE as most likely diagnosis by GPs.

Study design: prospective diagnostic cohort study.

Study population: this study will include 750 patients with subacute new onset or worsening of existing shortness of breath with or without chest symptoms, which makes them suspected of having PE.

Intervention: participants will be managed by their GP according to the YEARS-strategy. Furthermore, additional blood will be drawn for CRP. There will be a clinical follow-up in primary care for 3 months in all patients to establish the final diagnosis.

Doel van het onderzoek

The primary hypothesis is that a novel clinical decision rule for pulmonary embolism (the YEARS strategy) is at least as safe as previous studies, yet with an increased proportion of patients safely not referred for CTPA, thus fewer false-positive D-dimer tests

Onderzoeksopzet

There will be a clinical follow-up in primary care for 3 months in all patients to establish the final diagnosis.

Onderzoeksproduct en/of interventie

The intervention is a novel clinical decision rule for patients with a suspected pulmonary embolism: 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 the most likely diagnosis. 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 has a D-dimer below either threshold, PE is safely ruled out. Furthermore, additional blood will be drawn for CRP in order to quantify the added diagnostic value of CRP in the diagnostic management of PE.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Clinical suspicion of pulmonary embolism (PE), with complaints such as subacute new onset or worsening of existing shortness of breath or chest symptoms;

- Aged 18 years or older

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Pregnant;

- Already using anticoagulants (i.e. a vitamin K antagonist, low-molecular weight heparine or a direct oral anticoagulant);

- Life expectancy < 1 month

- Haemodynamic instability

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-09-2018
Aantal proefpersonen:	750
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-08-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52757
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7232
NTR-old	NTR7431
CCMO	NL64357.041.18
OMON	NL-OMON52757

Resultaten