Performance of a new, structured diagnostic algorithm for suspected pulmonary embolism in pregnant patients

Gepubliceerd: 29-06-2016 Laatst bijgewerkt: 18-08-2022

To evaluate the safety and efficiency of a new diagnostic strategy for pregnant patients with suspected pulmonary embolism

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28083

Bron
NTR

Verkorte titel
The Artemis study

Aandoening

Diagnosis, Pulmonary embolism, pregnancy

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)
Overige ondersteuning: Leiden University Medical Center (LUMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

(recurrent) PE, DVT, mortality

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: In non-pregnant patients, well established algorithms exist, including combination of clinical decision rule, D-dimer test and in case of a "likely" clinical decision rule or abnormal D-dimer test, computed tomography pulmonary angiography (CTPA) to rule out the diagnosis. This strategy is no option for pregnant patients since no validated pregnancy-specific clinical decision rules exist and D-dimer levels often rise physiologically in pregnancy. Current practice is to perform V-Q lung scan or CTPA as standalone test, but both have drawbacks. Recently, a new diagnosed algorithm for suspected PE was developed and validated (van Es et al, JTH 2015). We set out to evaluate the safety and efficiency of this algorithm in pregnant patients with suspected PE.

Objectives: 1) to validate the clinical utility and safety of the study algorithm by determining the three-months VTE incidence in pregnant patients in whom PE was excluded at baseline. 2) to assess the number of required CTPA and compare that to the numbers from historical cohorts.
Design: Prospective multicenter management study of consecutive pregnant patients with suspected (recurrent) PE. Participants will be evaluated according to the study algorithm consisting of three items of the original Wells rule (clinical signs DVT, hemoptysis, "PE most likely diagnosis") and a D-dimer test. In patients with clinical signs of DVT, a compression ultrasonography will be performed to rule out deep vein thrombosis. Patients with confirmed DVT are considered to have PE and anticoagulant treatment will be initiated. In the remaining patients without any of the three items and a D-dimer level < 1.0 µg/ml, and in patients with ≥ 1 items and a D-dimer level < 0.5 µg/ml PE is excluded without CTPA. In the other patients a CTPA will be performed. If PE is confirmed by CTPA, anticoagulant treatment will be initiated. If CTPA result is normal, PE is considered to be ruled out and anticoagulant therapy is withheld. All patients will be followed for a period of three months.

Doel van het onderzoek

To evaluate the safety and efficiency of a new diagnostic strategy for pregnant patients with suspected pulmonary embolism

Onderzoeksopzet

the primary and secondary endpoints will be determined after three months follow-up

Onderzoeksproduct en/of interventie

Prospective multicenter management study of consecutive pregnant patients with suspected (recurrent) PE. Participants will be evaluated according to the study algorithm consisting of three items of the original Wells rule (clinical signs DVT, hemoptysis, "PE most likely diagnosis") and a D-dimer test. In patients with clinical signs of DVT, a compression ultrasonography will be performed to rule out deep vein thrombosis. Patients with confirmed DVT are considered to have PE and anticoagulant treatment will be initiated. In the remaining patients without any of the three items and a D-dimer level < 1.0 µg/ml, and in patients with ≥ 1 items and a D-dimer level < 0.5 µg/ml PE is excluded without computed tomography pulmonary angiography (CTPA). In the other patients a CTPA will be performed. If PE is confirmed by CTPA, anticoagulant treatment will be initiated. If CTPA result is normal, PE is considered to be ruled out and anticoagulant therapy is withheld. All patients will be followed for a period of three months.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Pregnant patient with suspected (recurrent) pulmonary embolism

- age ¡Ý 18 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- treatment with full-dose therapeutic low molecular weight heparin or unfractionated heparin that was initiated 24 hours or more prior to eligibility assessment

- treatment with vitamin K antagonists (coumarin derivates)

- Ultrasonography proven symptomatic proximal DVT

- unable to give consent

- contraindication to helical CT because of allergy to intravenous iodinated contrast or renal insufficiency (creatinin clearance < 30 ml/min)

- impossibility to return for follow-up

- life expectancy < 3 months

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart

(Verwachte) startdatum:	16-09-2013
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-06-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5726
NTR-old	NTR5913
Ander register	: P13.151

Resultaten

Samenvatting resultaten

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