Randomized Evaluation of Patients With Stable Angina Comparing Diagnostic Examinations.

Gepubliceerd: 06-12-2011 Laatst bijgewerkt: 18-08-2022

This randomized, controlled, diagnostic, multicenter trial will compare two diagnostic imaging pathways--coronary computed tomography angiography (CCTA) and single photon emission tomography (SPECT) myocardial perfusion imaging (MPI)--to determine...

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25114

Bron
NTR

Verkorte titel
RESCUE

Aandoening

Chest Pain
Stable Angina Pectoris, CCS Class I to III
Angina Equivalent
Coronary Artery Disease

Ondersteuning

Primaire sponsor: American College of Radiology Imaging Network
Overige ondersteuning: American College of Radiology Imaging Network

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To compare outcomes of participants with symptoms of stable angina or angina equivalent evaluated with an anatomic imaging strategy using CCTA as initial method of CAD diagnosis (Group A) to a combined functional and anatomic imaging strategy of SPECT MPI/ICA (Group B) as a guide to OMT.

Toelichting onderzoek

Achtergrond van het onderzoek

The Randomized Evaluation of Patients with Stable Angina Comparing Utilization of Diagnostic Examinations (RESCUE) is a multi-center randomized, controlled trial responding to the need for comparative analysis of these imaging technologies and the role of OMT in clinical care. A total of 4300 patients will be randomized to CCTA or SPECT MPI/ICA for diagnostic assessment of angina at up to 80 institutions internationally. This study builds on the results of the COURAGE trial by comparing CCTA and SPECT MPI/ICA integrated into a care paradigm featuring initial treatment with OMT for patients diagnosed with CAD without significant disease in the left main coronary artery. Participants will be followed for a composite endpoint of MACE and cross-over to revascularization over a follow-up period up to two years (two to six time points depending on diagnostic results and time of enrollment into the trial). The primary endpoint of the study is a combined endpoint of occurrence of MACE and revascularization. We will calculate differences in the combined MACE/revascularization endpoint between the CCTA and SPECT MPI/ICA arms. Participant outcomes will be assessed by age, gender, comorbidity, and angina classification class at presentation. Several comparative-effectiveness analyses will be performed. We hypothesize that the CCTA arm will be associated with no increase in MACE or revascularization, decreased cost, reduced risks (e.g., less radiation exposure), additional insights into or alternate explanations of chest pain, and increased cost-effectiveness in comparison with SPECT MPI/ICA. Findings are expected to result in validation of an evolving new standard of care for patients with stable angina that takes advantage of CCTA and OMT to more cost-effectively drive appropriate care while reducing the need for invasive diagnosis and increased radiation exposure with SPECT MPI/ICA.

Doel van het onderzoek

This randomized, controlled, diagnostic, multicenter trial will compare two diagnostic imaging pathways--coronary computed tomography angiography (CCTA) and single photon emission tomography (SPECT) myocardial perfusion imaging (MPI)--to determine the incidence of major adverse coronary events (MACE), defined as myocardial infarction (MI) or cardiac-related death, and cross-over to revascularization. CCTA may be used to direct patients with symptoms of stable angina or angina equivalent to optimal medical therapy (OMT). The use

of CCTA as a diagnostic tool for angina symptoms will be associated with no increase in MACE or revascularization, decreased cost, reduced risks (e.g., less radiation exposure), additional insights into alternate explanations of chest pain, and increased cost-effectiveness in comparison with use of SPECT MPI/invasive coronary angiography (ICA).

Onderzoeksopzet

Outcomes comparison, prognostic indices and cost-effectiveness analysis for data up to 24 months.

Onderzoeksproduct en/of interventie

1. Device: CCTA;

2. Device: SPECT MPI/ICA.

Contactpersonen

Publiek

Center for Medical Imaging - North East Netherlands
Dept of Radiology
University of Groningen / University Medical Center Groningen
R. Vliegenthart
Groningen
The Netherlands

Wetenschappelijk

Center for Medical Imaging - North East Netherlands
Dept of Radiology
University of Groningen / University Medical Center Groningen
R. Vliegenthart
Groningen
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

1. Willing and able to provide a written informed consent;

2. 40 years or older;

3. Presentation with symptoms of stable angina (CCS Class I to III) or angina equivalent with or without known CAD;

4. Planned non-invasive imaging for CAD diagnosis;

5. Able to tolerate CCTA or SPECT MPI per randomization as required by protocol, to be performed at an ACRIN-qualified facility with a RESCUE-qualified scanner.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Prior revascularization;

2. Not suitable to undergo CT with an iodinated contrast agent;

3. Known allergy-like reaction to contrast media as defined by the American College of Radiology (ACR) (or moderate to severe allergic reactions to more than one allergen;

4. Renal failure, as determined by glomerular filtration rate (GFR) < 30 mL/min/1.73 m2 based on a serum creatinine level obtained within 28 days prior to registration;

5. Renal insufficiency at the time of enrollment, as determined by GFR 30 to 60 mL/min/1.73 m2 based on a serum creatinine level obtained within 28 days prior to registration, unless permitted by the institution's policy and/or ACR guidance for risk reduction strategies;

6. Atrial fibrillation or significant arrhythmia judged to potentially limit quality of CCTA;

7. Acute ischemia;

8. Acute myocardial infarction;

9. Severe myocardial ischemia: Known markedly positive exercise treadmill stress test (significant ST segment depressions or hypotensive response during stage I of the Bruce protocol);

10. Unable to suspend respiration for 15 seconds or to follow instructions to do so;

11. Unstable angina and symptoms refractory to maximal oral and intravenous medical

therapy (persistent CCS Class IV);

12. History of known left ventricular ejection fraction < 45%;

13. Pulmonary edema or heart failure unresponsive to standard medical therapy;

14. Pacemaker;

15. Valvular heart disease likely to require surgery in the next 18 months;

16. Congenital heart disease or cardiomyopathy likely to affect prognosis during follow up;

17. Significant systemic hypertension (blood pressure > 200/100 mm Hg) unresponsive to medical therapy;

18. Severe noncardiovascular comorbidity limiting survival (e.g., cancer or other life threatening illness for which the patient is expected to live less than 12 months);

19. Prior imaging evaluation for this episode of symptoms (e.g., SPECT MPI or CCTA within the previous 72 hours);

20. BMI > 40 kg/m2;

21. Pregnancy or intent to become pregnant (if a female is of childbearing potential—defined as a premenopausal female capable of becoming pregnant—a pregnancy test should be done prior to enrollment).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland
Status: Werving gestart

(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	4300
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL3033
NTR-old	NTR3181
Ander register	ACRIN4701 : NTC01262625
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A