Randomized Evaluation of Patients With Stable Angina Comparing Diagnostic Examinations.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25114

Source
NTR

Brief title
RESCUE

Health condition

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

Sponsors and support

Primary sponsor: American College of Radiology Imaging Network
Source(s) of monetary or material Support: American College of Radiology Imaging Network

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. To evaluate the ability of available prognostic indices to predict revascularization or MACE using CCTA information and to develop new indices using the RESCUE trial data;

2. To determine the cost, effectiveness, and incremental cost-effectiveness of CCTA versus SPECT MPI/ICA in the evaluation of participants with symptoms of stable angina;

3. To compare angina symptoms and self-reported health status of participants with symptoms of stable angina undergoing CCTA as initial method of CAD diagnosis to SPECT MPI/ICA as a guide to OMT.

Study description

Background summary

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.

Study objective

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).

Study design

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

Intervention

1. Device: CCTA;

2. Device: SPECT MPI/ICA.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-01-2011
Enrollment:	4300
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3033
NTR-old	NTR3181
Other	ACRIN4701 : NTC01262625
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A