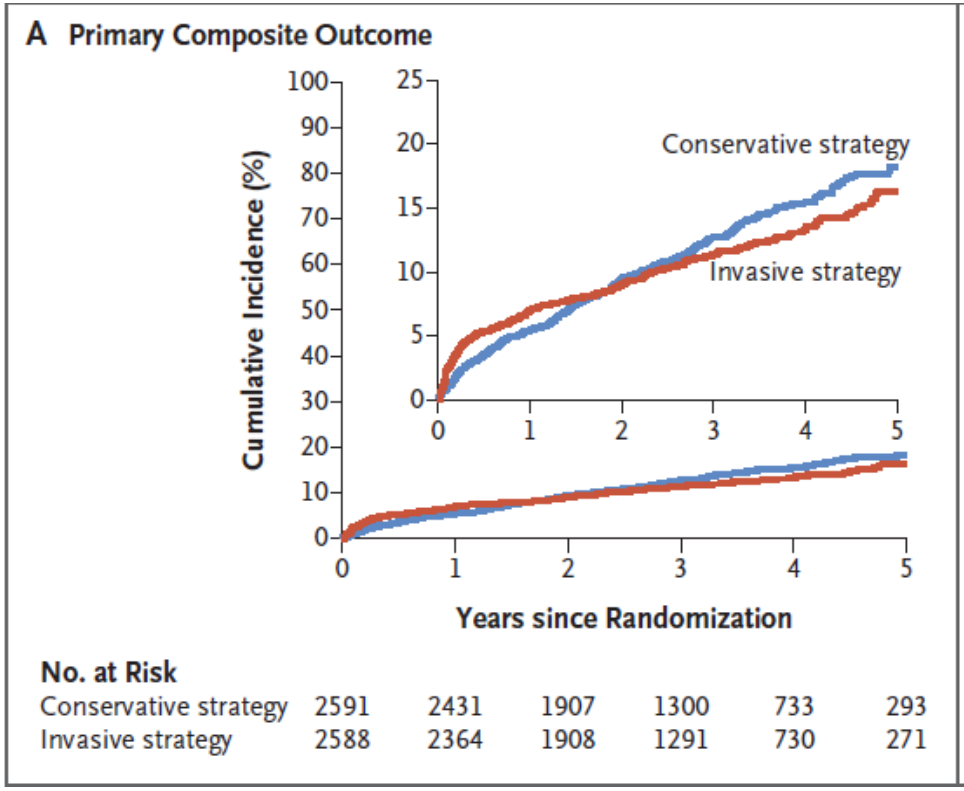
Proceduralの定義

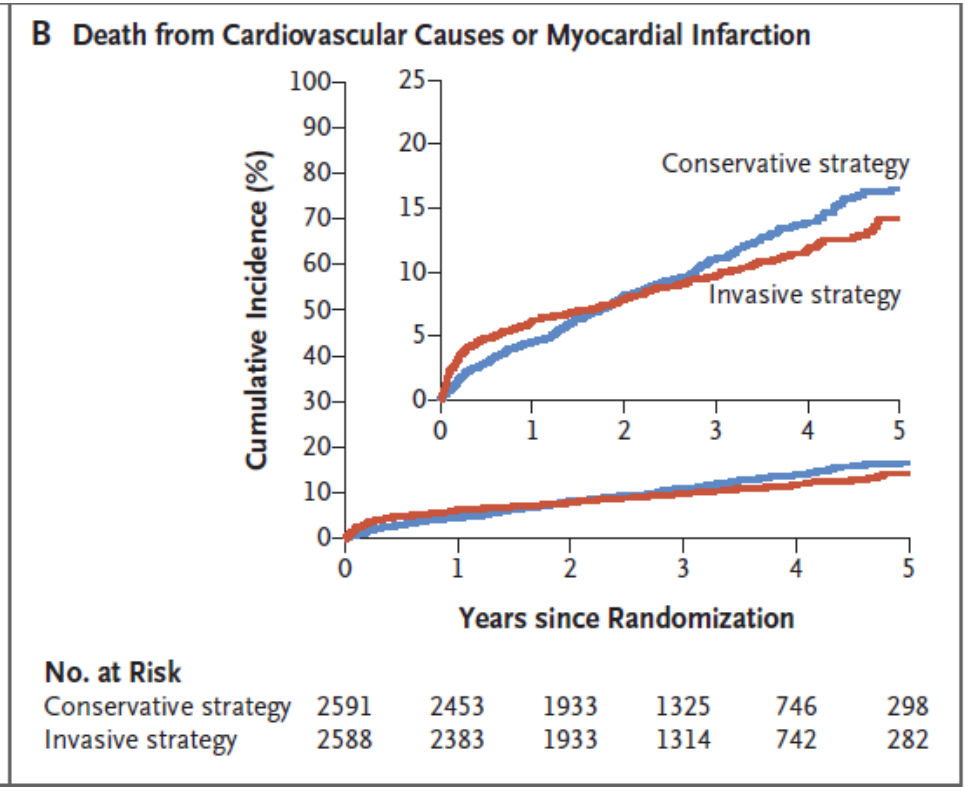
Confirmed MIs will be classified by the CEC using MI types provided by the UMI as follows:

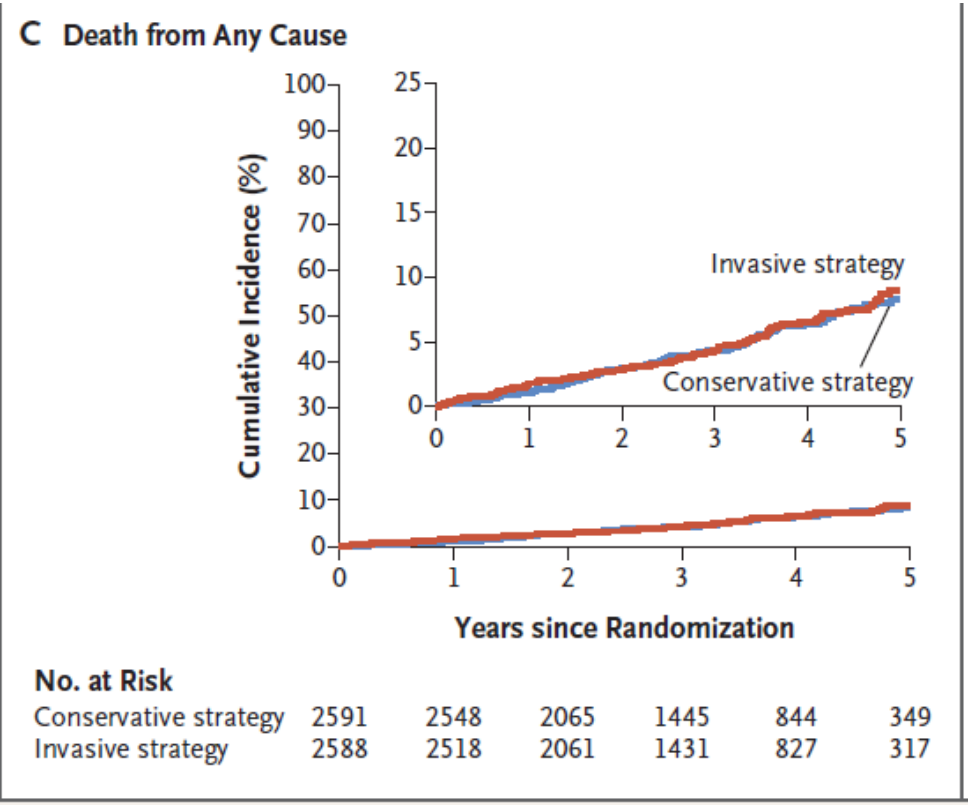
- Type 1: Spontaneous MI
- Type 2: Secondary MI
- Type 3: Sudden Death MI
- Type 4a: MI related to PCI
- Type 4b: MI related to stent thrombosis
- Type 4c: MI related to stent restenosis
- Type 5: MI related to CABG

There will be some secondary analyses that will group together several MI types. There will be two resulting groups of MI types that will be analyzed. One group will correspond to procedural MIs and include Type 4a and 5 MIs. The other group will correspond to non-procedural MIs and include Type 1, 2, 4b and 4c MIs.

Non-proceduralとは自然発生の心筋梗塞です


A Primary Composite Outcome
Cumulative Incidence (%)
Conservative strategy
Invasive strategy
Years since Randomization
No. at Risk
Conservative strategy 2591 2431 1907 1300 733 293
Invasive strategy 2588 2364 1908 1291 730 271


B Death from Cardiovascular Causes or Myocardial Infarction
Cumulative Incidence (%)
Conservative strategy
Invasive strategy
Years since Randomization
No. at Risk
Conservative strategy 2591 2453 1933 1325 746 298
Invasive strategy 2588 2383 1933 1314 742 282



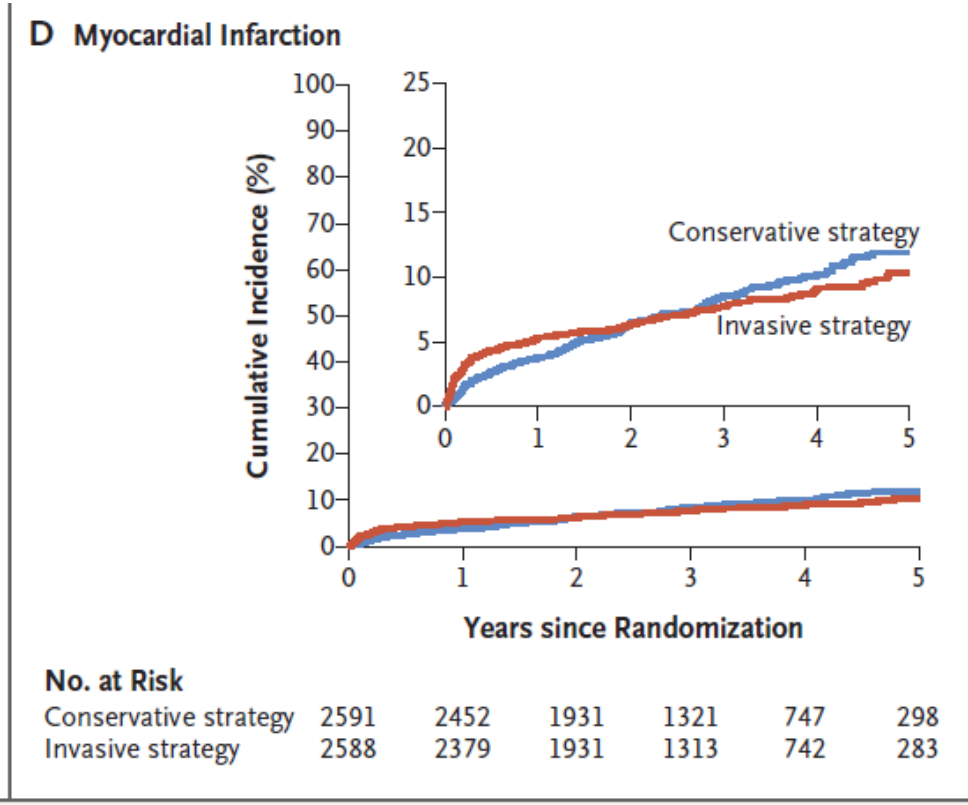


Figure 2. Time-to-Event Curves for the Primary Composite Outcome and Other Outcomes.

Panel A shows the cumulative incidence of the primary composite outcome of death from cardiovascular causes, myocardial infarction, or hospitalization for unstable angina, heart failure, or resuscitated cardiac arrest in the conservative-strategy group and the invasive-strategy group. Panel B shows the cumulative incidence of death from cardiovascular causes or myocardial infarction. Panel C shows the cumulative incidence of death from any cause, and Panel D shows the cumulative incidence of myocardial infarction. In each panel, the inset shows the same data on an enlarged y axis.

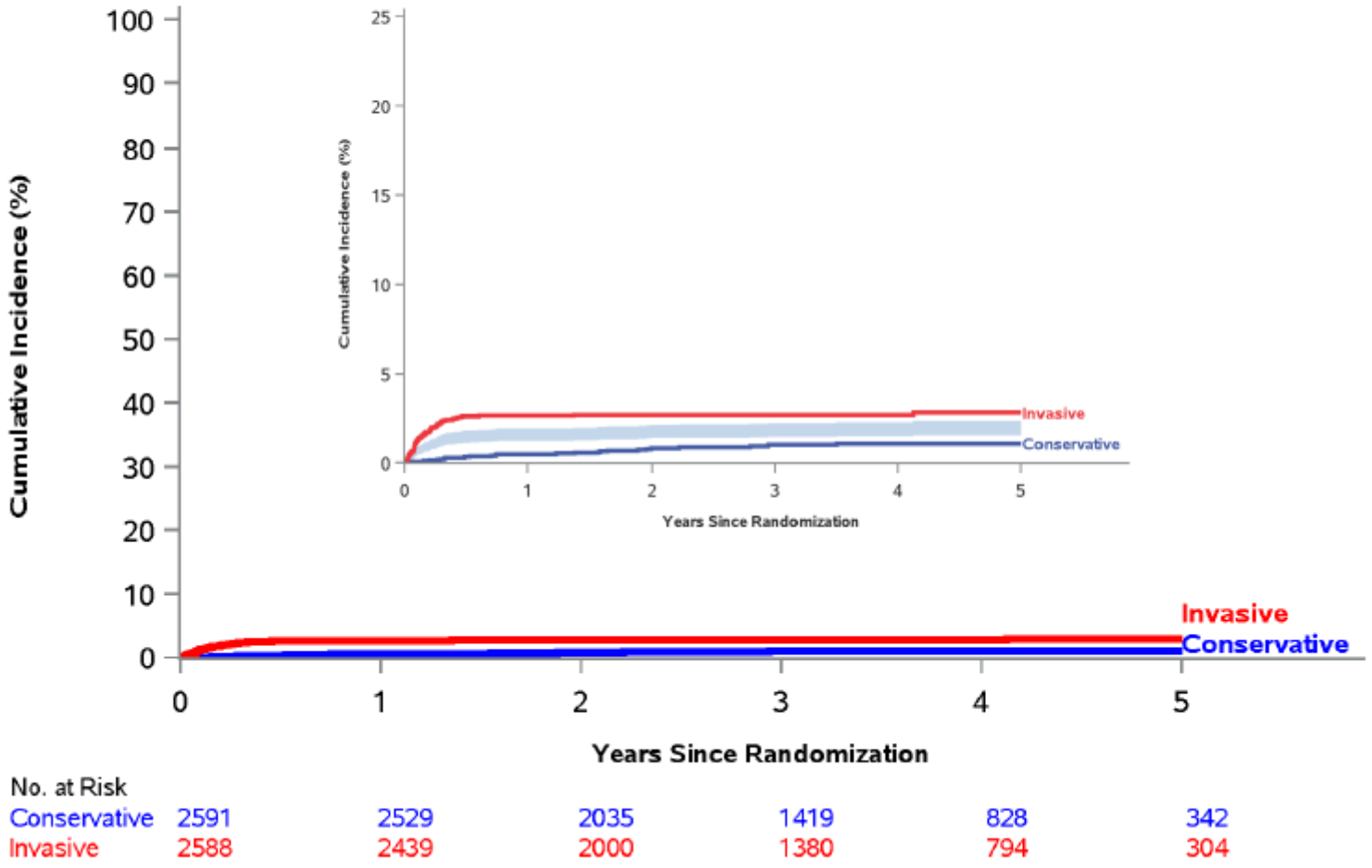
登録基準

Inclusion Criteria	• At least moderate ischemia on a stress imaging test with nuclear myocardial perfusion (≥10% myocardium), echo or cardiac magnetic resonance wall motion (≥3/16 segments with stress-induced severe hypokinesis or akinesis), or cardiac magnetic resonance perfusion (≥12% myocardium). • Participant is willing to comply with all aspects of the protocol, including adherence to medical therapy and follow-up visits • Participant is willing to give written informed consent
	• Age ≥ 21 years

除外基準

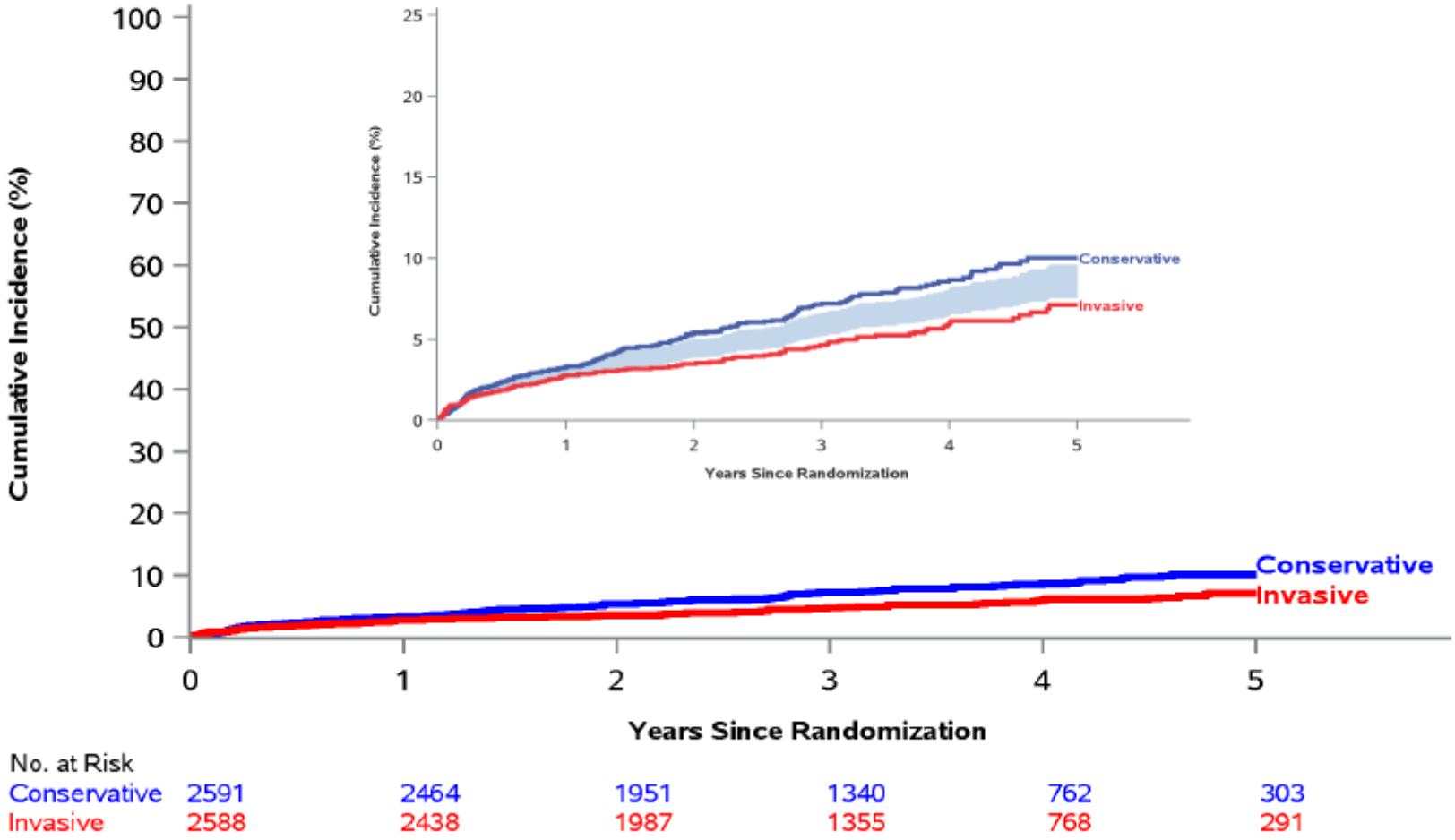
Exclusion Criteria	• LVEF < 35% • History of unprotected left main stenosis ≥50% on prior coronary computed tomography angiography (CCTA) or prior cardiac catheterization (if available). • Finding of "no obstructive CAD" (<50% stenosis in all major epicardial vessels) on prior CCTA or prior catheterization, performed within 12 months • Prior known coronary anatomy unsuitable for either PCI or CABG • Unacceptable level of angina despite maximal medical therapy • Very dissatisfied with medical management of angina • History of noncompliance with medical therapy • Acute coronary syndrome within the previous 2 months • PCI or CABG within the previous 12 months • Stroke within the previous 6 months or intracranial hemorrhage at any time • History of ventricular tachycardia requiring therapy for termination, or symptomatic sustained ventricular tachycardia • NYHA class III-IV heart failure at entry or hospitalization for exacerbation of chronic heart failure within the previous 6 months • Non-ischemic dilated or hypertrophic cardiomyopathy • End stage renal disease on dialysis or estimated glomerular filtration rate (eGFR) <30mL/min • Severe valvular disease or valvular disease likely to require surgery within 5 years • Allergy to radiographic contrast that cannot be adequately pre-medicated, or any prior anaphylaxis to radiographic contrast • Planned major surgery necessitating interruption of dual antiplatelet therapy • Life expectancy less than 5 years due to non-cardiovascular comorbidity • Pregnancy (known to be pregnant; to be confirmed before CCTA and/or randomization, if applicable)

Procedural MI



No. at Risk						
Conservative	2591	2529	2035	1419	828	342
Invasive	2588	2439	2000	1380	794	304

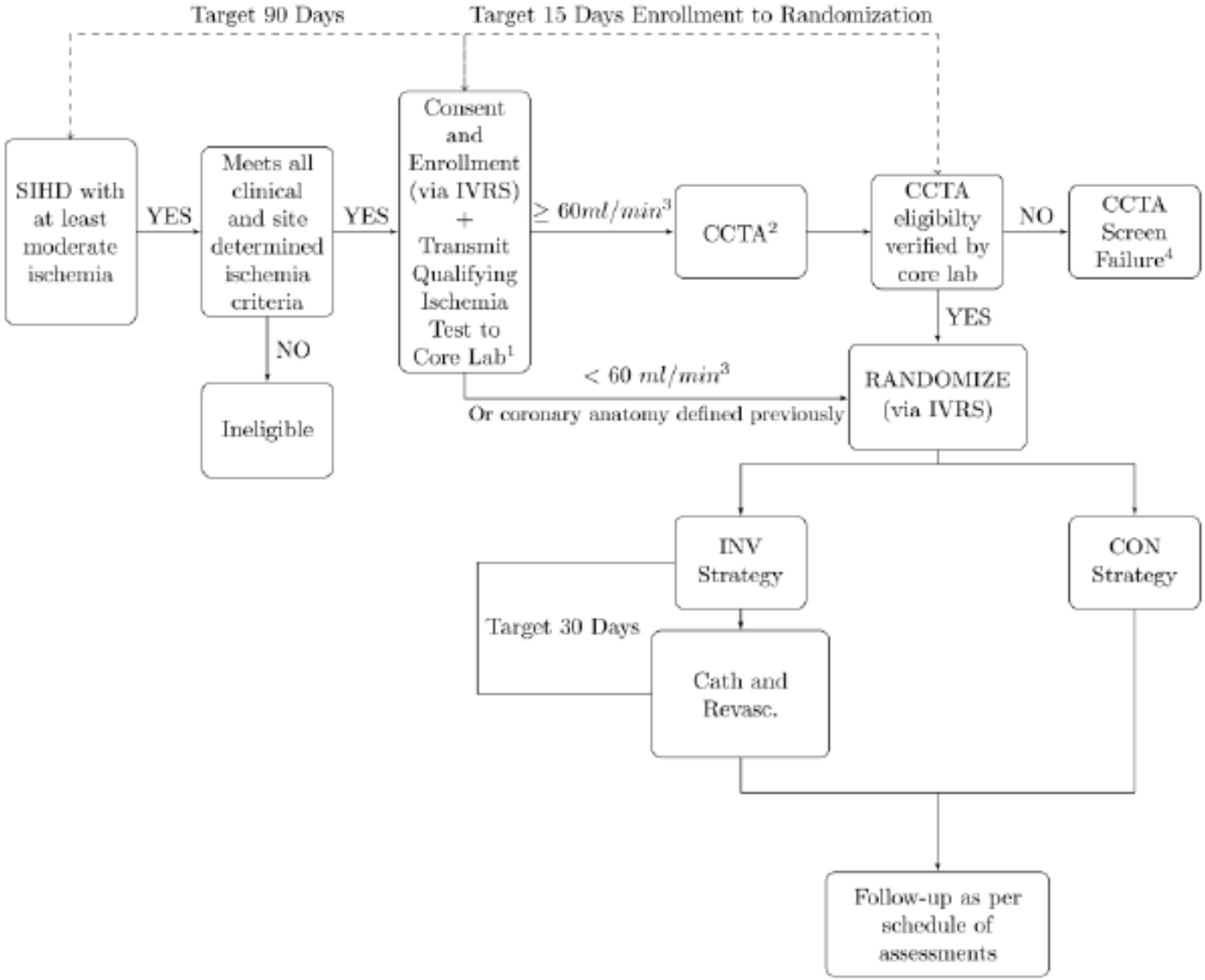
Non-procedural MI



No. at Risk						
Conservative	2591	2464	1951	1340	762	303
Invasive	2588	2438	1987	1355	768	291

IV. Supplementary Figures

Figure S1. Study Flow



[1] See MOO for measures to ensure randomization of participants who meet ischemia eligbility.

[2] CCTA will not be performed in participants with eGFR<60 ml/min or in participants who have had invasive angiography or CCTA within the prior 12 months (the number of patients enrolled with recent invasive angiography or CCTA may be capped)

[3] Participants with eGFR<60 ml/min with no clinical or ischemia testing characteristics suggestive of significant left main coronary artery stenosis are eligible to be randomized. Participants with eGFR<30 or on dialysis are included in the CKD ancillary trial. Some participants with eGFR≥60 may not undergo CCTA (see 6.5 and MOO). Some participants with eGFR<60 may undergo CCTA based on physician preference. Allowance of participants with exceptions to performance of CCTA relative to eGFR.

[4] CCTA screen failure due to no obstructive CAD will be enrolled in an ancillary study at participating sites. (CIAO-ISCHEMIA)

SIHD: Stable ischemic heart disease
CCTA: Coronary computed tomography angiography
IVRS: Interactive Voice Response Systems
INV: Invasive
CON: Conservative
MOO: Manual of Operations
eGFR: Estimated glomerular filtration rate
CKD: Chronic Kidney Disease
CIAO-ISCHEMIA: Ancillary study. Changes in Ischemia and Angina over One year among ISCHEMIA trial screen failures with no obstructive coronary artery disease on CT angiography.
CAD: Coronary artery disease