



High-Sensitive Troponin in the Evaluation of patients with Acute Coronary Syndrome (High-STEACS): a stepped-wedge cluster-randomised controlled trial

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High-STEACS Investigators



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Declaration of interest

- Consulting/Royalties/Owner/ Stockholder of a healthcare company (I have recieved horonaria from Abbott Diagnostics, Singulex and Roche all of whom manufacture cardiac troponin assays)
- Research contracts (The HighSTEACS trial is funded in full by a research charity, the British Heart Foundation, but Abbott Diagnostics provided reagent without charge to support the trial.)



Conclusions from the High-STEACS trial



- The High-STEACS trial is the first randomised controlled trial to evaluate the recommendations of the Global Task Force for the Universal Definition of Myocardial Infarction
- Implementation of high-sensitivity cardiac troponin and the recommended diagnostic threshold (99th centile of normal reference population) reclassified one in six patients as having myocardial injury, but only a third had a diagnosis of myocardial infarction and the rate of subsequent myocardial infarction or cardiovascular death at one year was unchanged
- Length of stay was doubled in patients, but halved in those without myocardial injury, and there was no evidence of excess treatment, bleeding or misdiagnosis



Fourth Universal Definition of Myocardial Infarction



“The term myocardial infarction should be used when there is evidence of myocardial necrosis in a clinical setting consistent with myocardial ischaemia, were myocardial necrosis is defined as a rise and/or fall in cardiac troponin with at least one value **>99th centile upper reference limit** of a healthy population”



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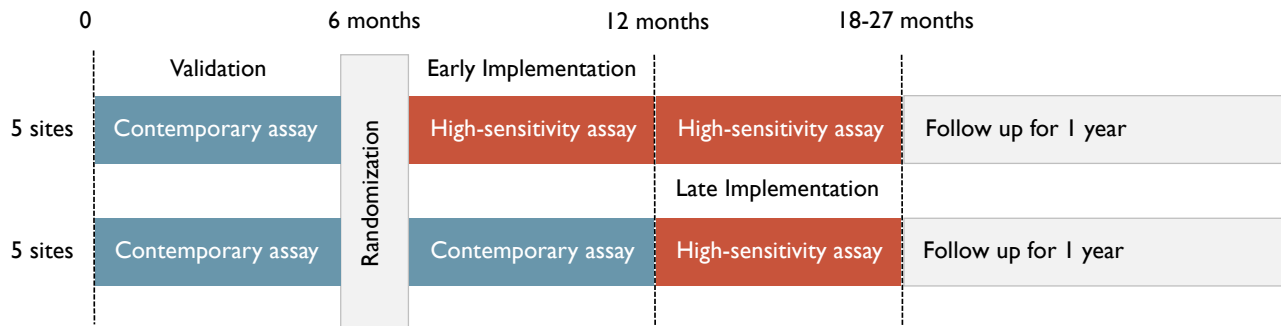
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Stepped-wedge cluster-randomised controlled trial



Aim: to determine whether implementation of high-sensitivity cardiac troponin I assay and a sex-specific 99th centile diagnostic threshold will reduce subsequent myocardial infarction or cardiovascular death at one year in consecutive patients with suspected acute coronary syndrome presenting to 10 secondary or tertiary care hospitals in Scotland

www.clinicaltrials.gov number: NCT01852123



Study population and results

48,282 consecutive patients with suspected acute coronary syndrome (61±17 years, 47% women)

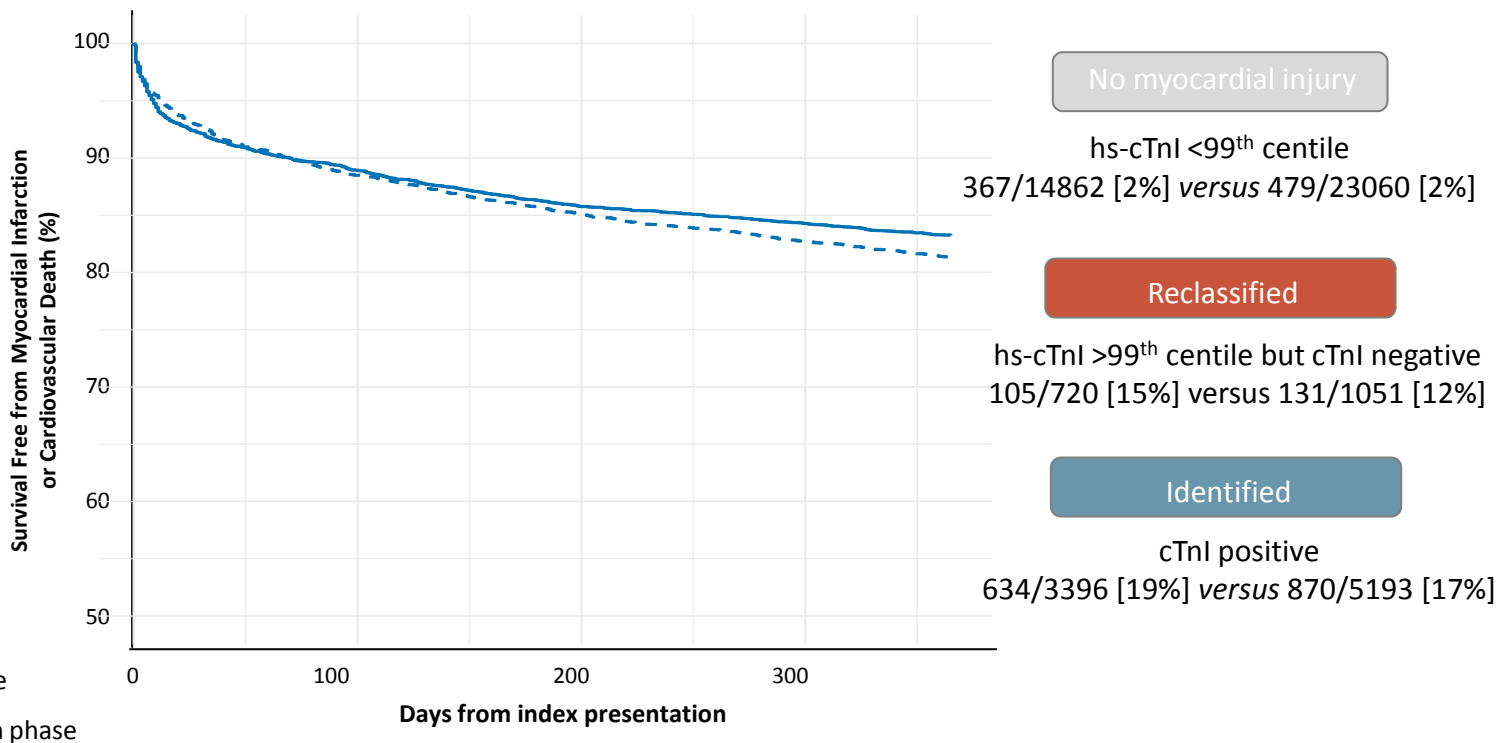
		Myocardial Injury (n = 10,360, 21%)	
	No myocardial injury	Reclassified by hs-cTnI	Identified by c-TnI
No. of participants	37,922 (79%)	1,771 (17%)	8,589 (83%)
Age	58±17	75±14	70±15
No. of women	17,571 (46%)	1,470 (83%)	3,521 (41%)
Chest pain	28,091 (84%)	1,074 (67%)	5,375 (71%)
Known ischaemic heart disease	8,455 (22%)	645 (36%)	2,812 (33%)
Diabetes mellitus	2,040 (5%)	218 (12%)	1,260 (15%)
eGFR, mL/min	56±10	47±15	48±16
Myocardial ischemia on ECG	-	194 (14)	2,316 (36)
Peak hs-cTnI, ng/L	3 [1-6]	26 [20-37]	297 [76-2,600]

Presented as No. (%), mean ± SD or median [inter-quartile range]; eGFR = estimated glomerular filtration rate



Primary outcome

Adjusted odds ratio for implementation versus validation phase 1.10, 0.75-1.61; P=0.620 *





Key messages



- The trial found that implementation of a high-sensitivity cardiac troponin test using the 99th centile as the diagnostic threshold increased the frequency of patients with myocardial injury; but only a third had a diagnosis of myocardial infarction, and outcomes for patients did not improve
- There was no evidence of misdiagnosis, inappropriate treatment, excess bleeding or harm following implementation of high-sensitivity cardiac troponin testing
- Length of stay was doubled in these patients, but halved in those without myocardial injury, and was reduced by one-third across the trial population suggesting clinicians were more confident ruling out myocardial infarction with potential benefits for healthcare providers
- Our findings question whether the diagnostic threshold for myocardial infarction should be based on the 99th centile derived from a normal reference population

