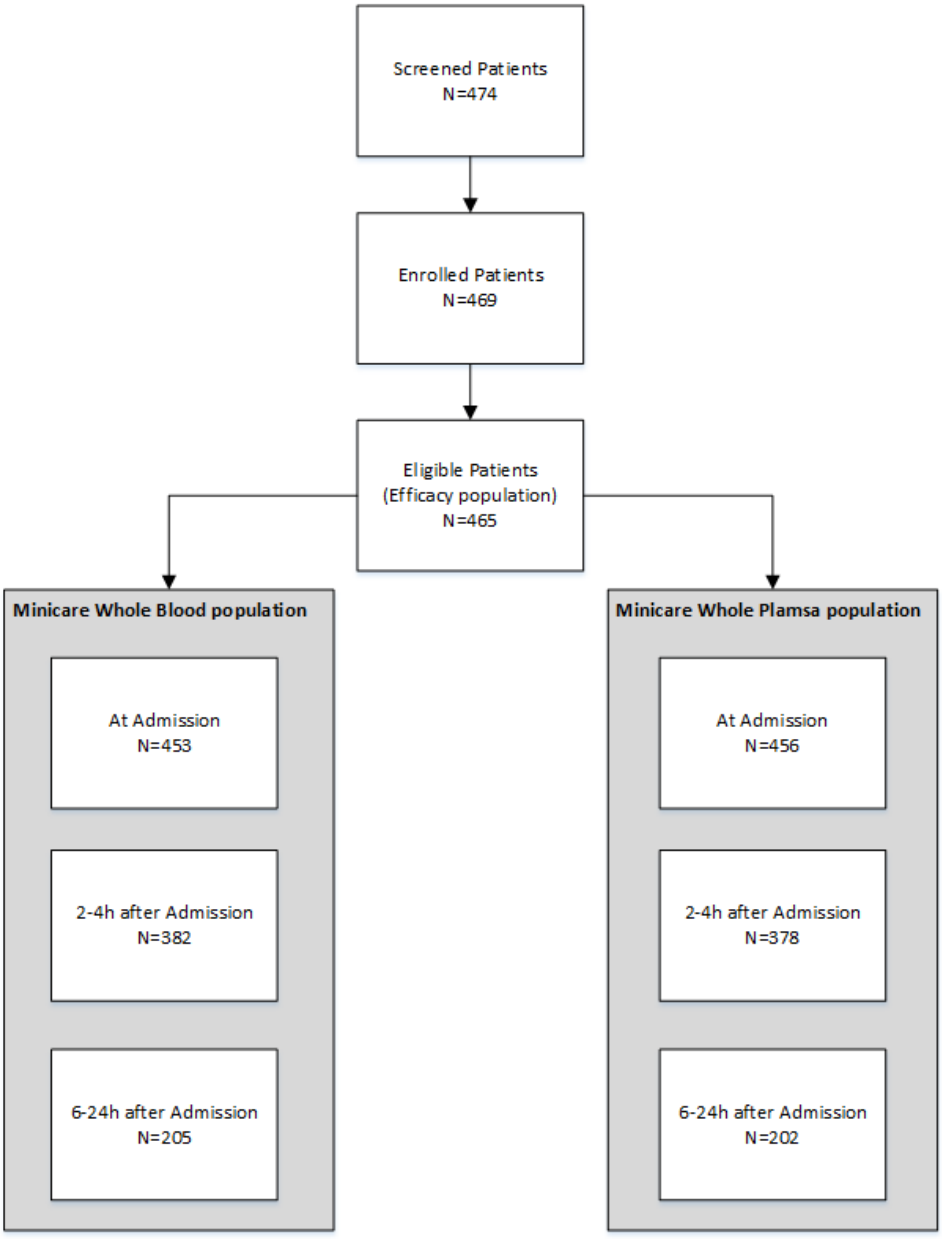
Participant Flow

The first patient was enrolled on 9 September 2015; the last subject was enrolled on 11 January 2016. From the total of 474 subjects screened, 469 were enrolled and 465 subjects were included in the efficacy population. The Enrolled population was defined as the subjects who signed the informed consent form and that satisfied all inclusion/exclusion criteria. The Efficacy population included all subjects with valid results obtained in the set time windows.



Reasons for missing a cTnI Li-heparin whole blood or Li-heparin plasma measurement at Admission were: 1) failure of the measurement; 2) blood tube was already sent to the lab for plasma measurement, or 3) the lab forgot to perform a measurement on the Li-heparin plasma since this was outside the hospital routine. The reason for missing cTnI sample measurements at 2-4h or 6-24h was early discharge of the patients since they were locally diagnosed to be AMI negative or transfer to another department/ location.

Baseline Characteristics

The subject demographics of the efficacy population is shown below:

	Total (N = 465)	AMI (N = 74)	Non-AMI (N = 392)
Age (years)			
N	465	74	391
Mean (SD)	61.6 (15.76)	68.3 (12.75)	60.3 (15.97)
Median	62.0	69.5	60.0
Min, Max	18, 94	28, 94	18, 92
Gender, n			
Male	275	59	216
Female	190	15	175
BMI (kg/m2)			
N	446	72	374
Mean (SD)	27.29 (5.03)	26.85 (4.31)	27.38 (5.16)
Median	26.42	26.16	26.52
Min, Max	15.85, 50.63	19.15, 46.06	15.85, 50.63

Below, additional baseline characteristic is shown.

Parameter	Total Subjects N = 465
Mean Height (SD) in cm	170.9 (9.41)
Mean Weight (SD) in kg	79.8 (16.18)
% Smokers (current and previous)	23.0
% Diabetes	22.2
% Peripheral Vascular Disease	7.3
% Cerebrovascular Disease	6.5
% hypertension	59.8
% hyperlipidaemia	39.8
% Coronary Artery Disease (CAD)	36.3
% Previous Myocardial Infarction (MI)	17.8
% Previous Percutaneous Coronary Intervention (PCI)	21.7
% Previous Coronary Artery Bypass Graft (CABG)	6.7
% Congestive Heart Failure (CHF)	10.3

Outcome Measures

Primary outcomes:

Sensitivity and specificity of Minicare cTnI was calculated using the 99th percentile URL value of 43 ng/L. Results of Li-Hep whole blood and plasma samples is shown in the tables below.

Li-heparin Whole Blood Samples Sensitivity and Specificity

Time cTnI measurement after admission	Sensitivity N/Total	Sensitivity (95 % CI)	Specificity N/Total	Specificity (95 % CI)
0h	49/71	69% 57% - 80%	355/382	93% 90%-95%
2-4h	60/65	92% 83%-98%	289/317	91% 88%-94%
6-24h	50/55	91% 80%-97%	130/150	87% 80%-92%

Sensitivity: N is total of True Positives and Total is True Positives plus False negatives
Specificity: N is total of True Negatives and Total is True Negatives plus False positives

Li-heparin Plasma Samples Sensitivity and Specificity

Time cTnI measurement after admission	Sensitivity N/Total	Sensitivity (95 % CI)	Specificity N/Total	Specificity (95 % CI)
0h	53/73	73% (61% - 82%)	356/383	93% 90%-95%
2-4h	58/64	91% (81%-97%)	283/314	90% 86%-93%
6-24h	52/57	91% (81%-97%)	124/145	86% 79%-91%

Sensitivity: N is total of True Positives and Total is True Positives plus False negatives
Specificity: N is total of True Negatives and Total is True Negatives plus False positives

Secondary outcomes:

The PPV and NPV were calculated using the 99th percentile URL value of 43 ng/L. Results of Li-Hep whole blood and plasma samples is shown in the tables below.

Li-heparin Whole Blood Samples PPV and NPV

Time cTnI measurement after admission	PPV N/Total	PPV (95 % CI)	NPV N/Total	NPV (95 % CI)
0h	49/76	65% 53%-75%	355/377	94% 91%-96%
2-4h	60/88	68% 57%-78%	289/294	98% 96%-99%
6-24h	50/70	71% 59%-82%	130/135	96% 92%-99%

PPV: N is total of True Positives and Total is True Positives plus False positives
NPV: N is total of True Negatives and Total is True Negatives plus False negatives

Li-heparin Plasma Samples PPV and NPV

Time cTnI measurement after admission	PPV N/Total	PPV (95 % CI)	NPV N/Total	NPV (95 % CI)
0h	53/80	66% 55%-76%	356/376	95% 92%-97%
2-4h	58/89	65% 54%-75%	283/289	98% 96%-99%
6-24h	52/73	71% 59%-81%	124/129	96% 91%-99%

PPV: N is total of True Positives and Total is True Positives plus False positives
NPV: N is total of True Negatives and Total is True Negatives plus False negatives

Adverse Events

There were no adverse events associated with this trial.