

PRIMARY ENDPOINT

The following table shows the results of the analysis for the primary endpoint using a Cox proportional hazards model in the intention-to-treat (ITT) population as described in the Statistical Analysis Plan (SAP) including: • Number of events • Incidences per patient-years • Hazard ratio with 95% confidence interval (adjusted for center using strata) • p-values for the different hypotheses, i.e. one-sided for the non-inferiority margin 1.3 and one-sided for superiority • the number of individuals included in the analysis

Table 01: Results of the analysis of primary time to event endpoint

Endpoint	Left atrial appendage closure	Physician-directed best medical care	Left atrial appendage closure vs. Physician-directed best medical care			N
	Events/ patient-years (incidence per 100 patient-years)	Events/ patient-years (incidence per 100 patient-years)	Adjusted hazard ratio (95% CI)	p-value (one- sided; margin HR=1.3)	p-value (one- sided; test HR=1)	
Primary Endpoint	155/920.8 (16.83)	127/957.0 (13.27)	1.28 (1.01, 1.62)	0.4408	0.9790	888

The cumulative incidences estimated with the Aalen-Johansen estimator to account for competing events are shown in the following figure.

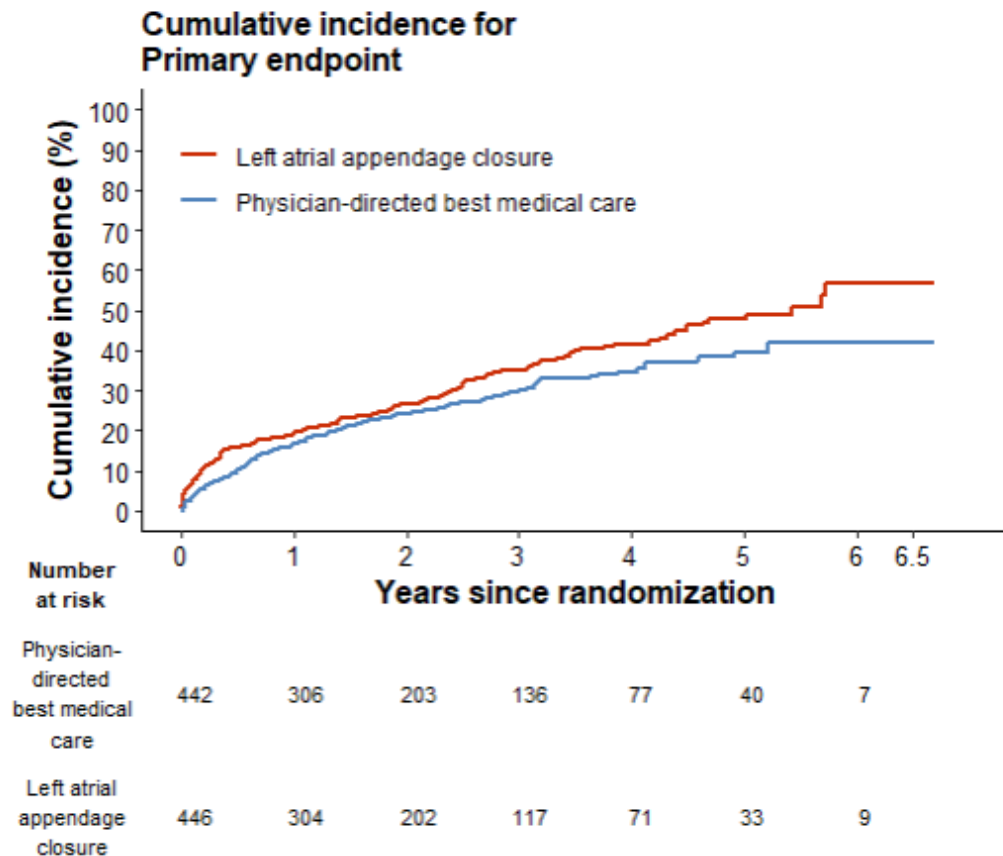


Figure 04: Aalen Johansen plot for primary endpoint