**Appendix D** – Trial sequential analysis for a) cumulative 24-hour oral morphine equivalent consumption and b) cumulative difference in area under the curve (AUC) rest pain over 24-hours. The red line represents the cumulative Z-score. The inward sloping red lines represent the trial sequential monitoring boundaries. The outward sloping red lines represent the futility region. The horizontal blue lines represent the threshold for significance.
Supplemental material

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b)

Sample Size is a Two-sided graph

Cumulative Z-Score

Favours BSEP

Favours Control

Number of patients (Linear scaled)

Sample Size = 1593

Z-curve

1178