**Additional file 1**

Additional file 1. Description of the assessed clinical trial designs.

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|  | **Single-arm*** **Historical comparison**
 | **Two-arm*** **Randomization 1:1**
 | **Statistical analyses**  |
| **Fixed design** | F1H0: $p\_{E} = p\_{H} $*vs*.H1: $p\_{E} > p\_{H}$ | F2H0: $p\_{E} = p\_{C} $*vs*.H1: $p\_{E} > p\_{C}$ | Unilateral Z tests If p-value < 0.025, significant test  |
| **Sequential design** | S1H0: Θ = 0 *vs.* H1: Θ > 0,with Θ$ = log\left[\frac{p\_{E}(1-p\_{H})}{p\_{H}(1-p\_{E})}\right]$ | S2H0: Θ = 0 *vs*. H1: Θ > 0,with Θ$ = log\left[\frac{p\_{E}(1-p\_{C})}{p\_{C}(1-p\_{E})}\right]$ | * Whitehead triangular tests
* Stopping boundaries defined with α = 0.025
* Significant test if the test statistic was superior to the upper stopping boundary
* Number of interim analyses defined a priori: every 20 patients included
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Abbreviations: $p\_{C}$indicates control survival rate; pH: pre-trial historical survival rate; $p\_{E}$: experimental survival rate; F1: fixed single-arm design; S1: group-sequential single-arm design; F2: fixed double-arm design; S2: group-sequential double-arm design.