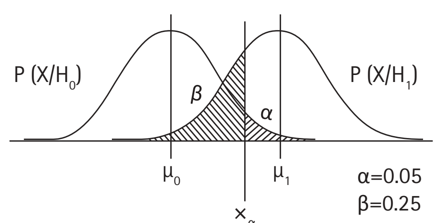
Supplementary material

Fundamental equations[8]

Parameter	Superiority trial	Inferiority trial
Purpose	Intervention is 'better' than control	Intervention is 'not worse' than control
H0 (null hypothesis)	$H_0: \mu_I - \mu_C = \delta$	$H_0: \mu_I - \mu_C = \delta$ Or $H_0: \mu_C - \mu_I = \delta$
Meaning	Intervention is better than control by a clinically admissible margin, delta	Intervention is worse than control by a clinically admissible margin, delta
H1 (alternative hypothesis)	$H_1: \mu_I - \mu_C > \delta$	$H_1: \mu_I - \mu_C > -\delta$
Meaning	Intervention is better than control by at least delta (a clinically admissible margin)	Intervention is NOT worse than control by delta (a clinically admissible margin), and can be better
Test statistic	$z = \frac{(d - \delta)}{\sigma}$	$z = \frac{(d - \delta)}{\sigma}$
Difference	Difference in effectiveness, $\mu_I - \mu_C$	Difference in effectiveness, $\mu_I - \mu_C$
N, sample size	$N = 2 \times \left[\frac{z_{1-\alpha} + z_{1-\beta}}{\delta - \delta_0}\right]^2 \times s^2$	$N = 2 \times \left[\frac{z_{1-\alpha} + z_{1-\beta}}{\delta_0}\right]^2 \times s^2$

Type 1 error, type 2 error, power



α Type I error: rejecting the null hypothesis when it's actually true usually 0.05, usually 2-sided
β Type II error: unable to reject H0 when it should be rejected
Power = 1 – β, usually set to 0.8

ASTER trial calculations

δ	Expected clinical difference – 15%
δ_0	Clinically significant difference – 5%
α	0.05
β	0.20
$z_{1-\alpha}$	1.645
$z_{1-\beta}$	0.842
N_{CS}	Sample size, clinical superiority
N_{NI}	Sample size, non-inferiority

ASTER, Direct Aspiration First Pass Technique for Thrombectomy Revascularization of Large Vessel Occlusion in Acute Ischemic Stroke.

Sample size calculations[9]

$$\frac{N_{CS}}{N_{NI}} = \frac{2 \times \left[\frac{z_{1-\propto} + z_{1-\beta}}{\delta - \delta_0}\right]^2 \times s^2}{2 \times \left[\frac{z_{1-\propto} + z_{1-\beta}}{\delta_0}\right]^2 \times s^2}$$

$$\frac{N_{CS}}{N_{NI}} = \frac{\cancel{2\times} \left[\frac{\cancel{z_{1-\propto} + z_{1-\beta}}}{\delta - \delta_0}\right]^2 \cancel{\times s^2}}{\cancel{2\times} \left[\frac{\cancel{z_{1-\propto} + z_{1-\beta}}}{\delta_0}\right]^2 \cancel{\times s^2}}$$

$$\frac{N_{CS}}{N_{NI}} = \frac{[\delta_0]^2}{[\delta - \delta_0]^2}$$

$$\frac{N_{CS}}{N_{NI}} = \frac{[0.05]^2}{[0.15 - 0.05]^2}$$

$$\frac{N_{CS}}{N_{NI}} = \frac{[0.05]^2}{[0.1]^2}$$

$$\frac{N_{CS}}{N_{NI}} = \frac{0.0025}{0.01}$$

$$\frac{N_{CS}}{N_{NI}} = \frac{25}{100} = \frac{1}{4}$$

$$N_{NI} = 4 \times N_{CS}$$

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