

Power Analysis of Non-Inferiority Tests of Two Independent Proportions

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Numeric Results for Non-Inferiority Tests Based on the Difference: P1 - P2

H0: P1-P2>=D0. H1: P1-P2=D1<D0. Test Statistic: Z test (unpooled)

Power	Sample Size Grp 1 N1	Sample Size Grp 2 N2	Grp 2 Prop P2	Equiv. Grp 1 Prop P1.0	Actual Grp 1 Prop P1.1	Equiv. Margin Diff D0	Actual Margin Diff D1	Target Alpha	Actual Alpha	Beta
<i>Power 80%, non-inferiority margin 2.5% for outcome MACE</i>										
0.8002	388	388	0.0200	0.0450	0.0200	0.0250	0.0000	0.0500		0.1998
0.8001	760	760	0.0400	0.0650	0.0400	0.0250	0.0000	0.0500		0.1999
0.8001	1116	1116	0.0600	0.0850	0.0600	0.0250	0.0000	0.0500		0.1999
0.8002	1457	1457	0.0800	0.1050	0.0800	0.0250	0.0000	0.0500		0.1998
0.8001	1781	1781	0.1000	0.1250	0.1000	0.0250	0.0000	0.0500		0.1999
0.8001	2090	2090	0.1200	0.1450	0.1200	0.0250	0.0000	0.0500		0.1999
0.8001	2383	2383	0.1400	0.1650	0.1400	0.0250	0.0000	0.0500		0.1999
<i>Power 80%, non-inferiority margin 5.0% for outcome MACE</i>										
0.8181	93	93	0.0200	0.0700	0.0200	0.0500	0.0000	0.0500		0.1819
0.8001	190	190	0.0400	0.0900	0.0400	0.0500	0.0000	0.0500		0.1999
0.8001	279	279	0.0600	0.1100	0.0600	0.0500	0.0000	0.0500		0.1999
0.8009	365	365	0.0800	0.1300	0.0800	0.0500	0.0000	0.0500		0.1991
0.8007	446	446	0.1000	0.1500	0.1000	0.0500	0.0000	0.0500		0.1993
0.8005	523	523	0.1200	0.1700	0.1200	0.0500	0.0000	0.0500		0.1995
0.8003	596	596	0.1400	0.1900	0.1400	0.0500	0.0000	0.0500		0.1997
<i>Power 90%, non-inferiority margin 5.0% for outcome MACE</i>										
0.9014	135	135	0.0200	0.0700	0.0200	0.0500	0.0000	0.0500		0.0986
0.9009	264	264	0.0400	0.0900	0.0400	0.0500	0.0000	0.0500		0.0991
0.9004	387	387	0.0600	0.1100	0.0600	0.0500	0.0000	0.0500		0.0996
0.9004	505	505	0.0800	0.1300	0.0800	0.0500	0.0000	0.0500		0.0996
0.9002	617	617	0.1000	0.1500	0.1000	0.0500	0.0000	0.0500		0.0998
0.9002	724	724	0.1200	0.1700	0.1200	0.0500	0.0000	0.0500		0.0998
0.9000	825	825	0.1400	0.1900	0.1400	0.0500	0.0000	0.0500		0.1000

Summary Statements

Sample sizes of 388 in group one and 388 in group two achieve 80% power to detect a non-inferiority margin difference between the group proportions of 0.025. The reference group proportion is 0.02. The treatment group proportion is assumed to be 0.045 under the null hypothesis of inferiority. The power was computed for the case when the actual treatment group proportion is 0.02. The test statistic used is the one-sided Z test (unpooled).

Note: exact results based on the binomial were only calculated when both N1 and N2 were less than 100.

References

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Report Definitions

'Power' is the probability of rejecting a false null hypothesis. It should be close to one.

'N1 and N2' are the sizes of the samples drawn from the corresponding groups.

'P2' is the response rate for group two which is the standard, reference, baseline, or control group.

'P1.0' is the smallest treatment-group response rate that still yields a non-inferiority conclusion.

'P1.1' is the treatment-group response rate at which the power is calculated.

'D0' is the non-inferiority margin. It is the difference P1-P2 assuming H0.

'D1' is the actual difference, P1-P2, at which the power is calculated.

'Target Alpha' is the probability of rejecting a true null hypothesis that was desired.

'Actual Alpha' is the value of alpha that is actually achieved.

'Beta' is the probability of accepting a false H0. $\text{Beta} = 1 - \text{Power}$.

'Grp 1' refers to Group 1 which is the treatment or experimental group.

'Grp 2' refers to Group 2 which is the reference, standard, or control group.

'Equiv.' refers to a small amount that is not of practical importance.

'Actual' refers to the true value at which the power is computed.