Chapter 333

Multi-Arm Superiority by a Margin Tests for the Ratio of Treatment and Control Means (Normal Data)

Introduction

This module computes power and sample size for multiple superiority by a margin tests of treatment means versus a control mean when the data are assumed to follow the normal distribution and the statistical hypotheses are expressed in terms of mean ratios. Note that when the data follow a log-normal distribution rather than the normal distribution so that a log transformation is used, you should use other PASS procedures that assume a log-normal data distribution.

The details of this t-test are given in Rothmann, Wiens, and Chan (2012) and, to lesser extent, in Kieser and Hauschke (1999). The multiple comparison aspect of this procedure is based on the results in Machin, Campbell, Tan, and Tan (2018).

In this parallel-group design, there are *k* treatment groups and one control group. A mean is measured in each group. A total of *k* hypothesis tests are anticipated, each comparing a treatment group with the common control group using a t-test based on the ratio of two means.

The Bonferroni adjustment of the type I error rate may be optionally made because several comparisons are being tested using the same data. Making a multiplicity adjustment is usually recommended, but not always. In fact, Saville (1990) advocates not applying it and Machin, Campbell, Tan, and Tan (2018) include omitting it as a possibility.

Background

Whether you want to test several doses of a single treatment or several types of treatments, good research practice requires that each treatment be compared with a control. A popular three-arm design consists of three groups: control, treatment A, and treatment B. Two tests are run: treatment A versus control and treatment B versus the same control. This design avoids having to obtain a second control group for treatment B. Besides the obvious efficiency in subjects, it may be easier to recruit subjects if their chances of receiving the new treatment are better than 50-50.

Multi-Arm Superiority by a Margin Tests for the Ratio of Treatment and Control Means (Normal Data)

Technical Details

Suppose you want to compare k treatment groups with means μ_i and sample sizes N_i and one control group with mean μ_C and sample size N_C . The total sample size is $N = N_1 + N_2 + \cdots + N_k + N_C$.

Superiority by a Margin Tests

A superiority by a margin test tests that the treatment mean is better than the control mean by more than the superiority margin. The actual direction of the hypothesis depends on the response variable being studied. Define $R = \mu_i/\mu_C$.

Case 1: High Values Good

In this case, higher response values are better. The hypotheses are arranged so that rejecting the null hypothesis implies that the treatment mean is greater than the control mean by at least a small amount. This results in a superiority boundary called R_U . The null and alternative hypotheses with are

$$H_0: R \leq R_U$$
 vs. $H_1: R > R_U$

where $R_U > 1$.

Case 2: High Values Bad

In this case, lower values are better. The hypotheses are arranged so that rejecting the null hypothesis implies that the treatment mean is less than the control mean by at least a small amount. This results in a superiority boundary called R_L . The null and alternative hypotheses with are

$$H_0: R \ge R_L$$
 vs. $H_1: R < R_L$

where $R_L > 1$.

Equal-Variances T-Test Statistic

The ratio hypotheses are rearranged as from

$$H_0: \frac{\mu_i}{\mu_C} \le R_U$$
 vs. $H_1: \frac{\mu_i}{\mu_C} > R_U$

to

$$H_0: \mu_i - R_U \mu_C \le 0$$
 vs. $H_1: \mu_i - R_U \mu_C > 0$

The null hypothesis is tested using the test statistic

$$T_1 = \sqrt{\frac{\bar{X}_i - R_U \bar{X}_C}{S\left(\frac{1}{N_i} + \frac{R_L^2}{N_C}\right)}}$$

Multi-Arm Superiority by a Margin Tests for the Ratio of Treatment and Control Means (Normal Data)

where \bar{X}_i and \bar{X}_C are the sample means of the treatment and control groups, and S is the pooled estimate of the standard deviation, σ which is given by

$$S^{2} = \frac{(N_{i} - 1)s_{i}^{2} + (N_{C} - 1)s_{C}^{2}}{N_{i} - N_{C} - 2}$$

It is assumed that T_1 is distributed as a central t distribution with degrees of freedom given by $N_i + N_C - 2$. For a specified alternative R_1 , T_1 follows the noncentral t distribution with $N_i + N_C - 2$ degrees of freedom and noncentrality

$$\left(\frac{R_1 - R_U}{CV}\right) \sqrt{\frac{N_C}{\frac{N_C}{N_i} + R_U^2}}$$

Hence, the power of this test is given by noncentral t distribution as follows

$$(1 - \beta) = \Pr(T_1 \ge t_{1-\alpha,N_i+N_C-2} | R_1, R_{LU}, CV, N_C, N_i)$$

Multiplicity Adjustment

Because *k* t-tests between treatment groups and the control group are run when analyzing the results of this study, many statisticians recommend that the Bonferroni adjustment be applied. This adjustment is easy to apply: the value of alpha that is used in the test is found by dividing the original alpha by the number of tests. For example, if the original alpha is set at 0.05 and the number of treatment (not including the control) groups is five, the individual tests will be conducted using an alpha of 0.01.

The main criticism of this procedure is that if there are many tests, the value of alpha becomes very small. To mitigate against this complaint, some statisticians recommend separating the treatment groups into those that are of primary interest and those that are of secondary interest. The Bonferroni adjustment is made by the using the number of primary treatments rather than the total number of treatments.

There are some who advocate ignoring the adjustment entirely in the case of randomized clinical trials. See for example Saville (1990) and the discussion in chapter 14 of Machin, Campbell, Tan, and Tan (2018).

Size of the Control Group

Because the control group is used over and over, some advocate increasing the number of subjects in this group. The standard adjustment is to include \sqrt{k} subjects in the control group for each subject in one of the treatment groups. See Machin, Campbell, Tan, and Tan (2018, pages 231-232). Note that often, the treatment groups all have the same size.

Multi-Arm Superiority by a Margin Tests for the Ratio of Treatment and Control Means (Normal Data)

Example 1 - Finding the Sample Size

A parallel-group clinical trial is being designed to compare three treatment therapies against the standard therapy. Higher values of the response are desirable. Suppose the standard therapy has a mean response of 9.3 with a standard deviation of 2.5. The investigators would like a sample size large enough to find statistical significance at the 0.025 level (since this a one-sided test) if the actual mean responses of the three treatments are 12.2, 12.4, and 12.6, the power of each test is 0.80, and the superiority limit is 1.25. They want to consider a range of standard deviations from 2.0 to 3.0.

Following standard procedure, the control group multiplier will be set to $\sqrt{k} = \sqrt{3} = 1.732$ since the control group is used for three comparisons in this design.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 1** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Solve For	Sample Size
Higher Means Are	Better (H1: R > RU)
Power of Each Test	0.8
Overall Alpha	0.025
Bonferroni Adjustment	Standard Bonferroni
Group Allocation	Enter Group Allocation Pattern, solve for group sample sizes
RU (Upper Superiority Limit)	1.25
Control Mean	9.3
Control Sample Size Allocation	1.732
Set A Number of Groups	1
Set A Mean	12.2
Set A Sample Size Allocation	1
Set B Number of Groups	1
Set B Mean	12.4
Set B Sample Size Allocation	1
Set C Number of Groups	1
Set C Mean	12.6
Set C Sample Size Allocation	1
Set D Number of Groups	0
More	Unchecked
σ (Standard Deviation)	2 2.5 3

Multi-Arm Superiority by a Margin Tests for the Ratio of Treatment and Control Means (Normal Data)

Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Reports

Numeric Results

Solve For: Sample Size

Group Allocation: Enter Group Allocation Pattern, solve for group sample sizes

Test Type: Equal-Variance T-Test

Higher Means Are: Better

Hypotheses: H0: R ≤ RU vs. H1: R > RU

Number of Groups: 4
Bonferroni Adjustment: Standard Bonferroni (Divisor = 3)

	ъ.			mala Cina		Maan	Upper	Cton doud	Coefficient	,	Alpha
Comparison	Target	ower ————————————————————————————————————	———Ni	Allocation	Mean µi	Mean Ratio Ri	Superiority Limit RU	Standard Deviation σ	Coefficient of Variation COVi	Overall	Bonferroni- Adjusted
Control			419	1.732	9.3			2.0	0.21505		
vs A	0.8	0.80169	242	1.000	12.2	1.31183	1.25	2.0	0.16393	0.025	0.00833
vs B	0.8	0.97576	242	1.000	12.4	1.33333	1.25	2.0	0.16129	0.025	0.00833
vs C	0.8	0.99903	242	1.000		1.35484	1.25	2.0	0.15873	0.025	0.00833
otal	0.0	0.55503	1145	1.000	12.0	1.33404	1.23	2.0	0.13073	0.023	0.00033
Control			653	1.732	9.3			2.5	0.26882		
vs A	0.8	0.80052	377	1.000		1.31183	1.25	2.5	0.20492	0.025	0.00833
vs A vs B	0.8	0.80032	377	1.000	12.4	1.33333	1.25	2.5	0.20492	0.025	0.00833
vs C	0.8	0.97546	377	1.000	12.4	1.35484	1.25	2.5	0.19841	0.025	0.00833
otal	0.0	0.99901	1784	1.000	12.0	1.55404	1.20	2.0	0.13041	0.023	0.00033
Control			940	1.732	9.3			3.0	0.32258		
vs A	0.8	0.80055	543	1.000	12.2	1.31183	1.25	3.0	0.24590	0.025	0.00833
vs B	0.8	0.97551	543	1.000	12.4	1.33333	1.25	3.0	0.24194	0.025	0.00833
vs C	0.8	0.99901	543	1.000	12.6	1.35484	1.25	3.0	0.23810	0.025	0.00833
otal	0.0	0.00001	2569	1.000	12.0	1.00 10 1	1.20	0.0	0.20010	0.020	0.00000
Comparison	•							reatment ar	d control disp	layed on	this report
•		line. The	comp	arison is ma	de usin	g the ratio	•				
Comparison arget Powe		line. The The powe	compa r desire	arison is ma ed. Power is	de usin probab	g the ratio ility of reje	•		nd control dispension		
arget Powe		line. The The powe is of the	compa compa	arison is ma ed. Power is rison showr	de using probab on this	g the ratio ility of reje	•				
arget Powe	, -	line. The The powe is of the The powe	e compa r desire compa r actua	arison is ma ed. Power is rison shown lly achieved	de using probab on this	g the ratio ility of reje line only.	cting a false	null hypoth	esis for this co	ompariso	n. This powe
arget Powe	, -	line. The The powe is of the The powe The numb	compardesire compardesire compardesiresitesis compardissing compardesiresitesis compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compardissing compar	arison is ma ed. Power is rison shown ly achieved ubjects in the	de using probab on this e ith gro	g the ratio ility of reje line only. oup. The to	cting a false	null hypoth		ompariso	n. This powe
arget Powe Actual Power	· ·	line. The The powe is of the The powe The numb sum of a	e compar desire compar actua er of su	arison is ma ed. Power is rison shown lly achieved ubjects in the idual group	de using probab on this e ith grossample	g the ratio ility of reje line only. oup. The to sizes.	cting a false otal sample s	null hypoth	esis for this co	omparisoi ups is equ	n. This powe
arget Powe	· ·	line. The The powe is of the The powe The numb sum of a The group	e compar r desire compar r actua er of su all indiv	arison is ma ed. Power is rison shown lly achieved ubjects in the dual group e size alloca	de using probab on this e ith grossample attion rat	g the ratio ility of rejection only. Jup. The to sizes. Jup of the it	cting a false otal sample s	null hypoth	esis for this co	omparisoi ups is equ	n. This powe
arget Powe Actual Power Ii	· ·	line. The The powe is of the The powe The numb sum of a The group number	e compar r desire compar r actua er of su all indiv sampl of subj	arison is ma ed. Power is rison shown lly achieved. ubjects in the dual group se e size alloca ects assigne	de using probab on this e ith grossample ation rated to the	g the ratio ility of rejections. The to sizes. io of the ite group.	cting a false otal sample s h group. The	null hypothize shown by	esis for this concellow the ground	omparison ups is equ sents the	n. This power all to the relative
Target Power Actual Power Ali Allocation		line. The fine power is of the The power The number sum of a The group number The mean mean.	e compar desire compar actua er of su sampl of subj	arison is ma ed. Power is rison shown ly achieved ubjects in the dual group se e size alloca ects assigne ith group at	de using probab on this eith grossample ation rated to the which the	g the ratio ility of reje line only. up. The to sizes. io of the it group. ne power	cting a false otal sample s h group. The s computed.	null hypothize shown by value on earthe first ro	esis for this co	omparison ups is equ sents the	n. This power all to the relative
arget Powe Actual Power Ii		line. The The powe is of the The powe The numb sum of a The group number The mean mean.	e compar desire compar actua er of su sampl of subj	arison is ma ed. Power is rison shown ly achieved ubjects in the dual group se e size alloca ects assigne ith group at	de using probab on this eith grossample ation rated to the which the	g the ratio ility of reje line only. up. The to sizes. io of the it group. ne power	cting a false otal sample s h group. The	null hypothize shown by value on earthe first ro	esis for this concellow the ground	omparison ups is equ sents the	n. This power all to the relative
Target Power Actual Power Ali Allocation	· · · · · · · · · · · · · · · · · · ·	line. The The powe is of the The powe The numb sum of a The group number The mean mean. The ratio of the the mean of the mean of the the ratio of the	e compar desire compar actua er of suall individual of subjort the note that the control of the note that	arison is ma ed. Power is rison shown ly achieved ubjects in the dual group se e size alloca ects assigne ith group at	de using probab on this e ith grosample ation rated to the which the probab of the pro	g the ratio ility of rejet line only. The to sizes. To of the it group. The power is cover is cover is cover is cover	cting a false otal sample so h group. The scomputed.	null hypothize shown by value on earthe first ro	esis for this concellow the ground	omparison ups is equ sents the	n. This power
Target Power Actual Power Allocation II		line. The fine power is of the power the number sum of a fine group number. The mean mean. The ratio of the upper sum of the upper fine mean fine fine upper fine mean fine fine upper fine mean.	e compardesire compardesire actual er of stall indiversample of subject the notes that the control of the notes actual the notes a	arison is ma d. Power is rison showr ly achieved ubjects in the dual group a e size alloca ects assigne ith group at neans at whi ority limit for	de using probab on this e ith grosample tion rated to the which the part of the me	g the ratio dility of rejection only. The to sizes. In order to group. The it is group. The power is common order or an ratio. It is a size of the it is group.	cting a false otal sample s h group. The s computed. alculated. Ri RU > 1.	null hypoth ize shown by value on ear The first ro = μ i / μ c.	esis for this concellow the ground	omparison ups is equ sents the	n. This power
Target Power Actual Power Allocation III	· · ·	line. The fine power is of the power the number sum of a fine group number. The mean mean. The ratio of the upper the stand	e compardesire compardesire actual er of sull indiversity of the not superiord and device compard device compardesire compares compa	arison is ma id. Power is rison showr ly achieved abjects in the idual group are esize alloca eith group at heans at whi ority limit for viation of the	de using probab on this e ith grosample ato the which the characteristic the mean response.	g the ratio dility of rejection only. The to sizes. In order to size of the it is group. The power of the it is group. The power is contained to the size of the it is group. The power is contained to the size of the size	cting a false otal sample s h group. The s computed. alculated. Ri RU > 1. h each group	null hypoth ize shown by value on ear The first ro = μ i / μ c.	esis for this concellow the ground	omparison ups is equ sents the	n. This power all to the relative
Target Power Actual Power Allocation II	· · · · · · · · · · · · · · · · · · ·	line. The The powe is of the The powe The numb sum of a The group number The mean mean. The ratio of The upper The stand The coeffi The proba	e compar r desire compar r actua er of suall indive sample of subject of the not superiard devicient of	arison is mand. Power is rison shown by achieved abjects in the dual group elects assigned the group at the areas at who ority limit for viation of the variation of	de using probab on this on this e ith grosample ation rated to the which the characteristic the metersport the ith e using probability.	g the ratio dility of rejection only. The to sizes. The to sizes. The group. The it is group. The power is compared to the property of the pr	cting a false of tall sample so the group. The somputed. alculated. Ri RU > 1. to each group bVi = σ / μi.	null hypoth ize shown b value on ea The first ro = µi / µc.	esis for this concellow the ground	omparison ups is equ sents the c, the conf	n. This power all to the relative arol group
Target Power Actual Power Allocation III RI COVI		line. The free js of the js of the js of the js of the sum of a free group number the mean. The ratio of the upper the stand the coeffific js true.	e compar desire compar actua er of suall indivorsampl of subj of the not superiard devicient of billity of billity of the lates.	arison is mand. Power is rison shown ly achieved abjects in the dual group elected assigned it in group at the areas at white ority limit for variation of the variation of the rejecting at	de using probab on this on this eith grossample attorned to the which the characteristic the metresport the ith least o	g the ratio dility of rejection only. The to sizes. The to sizes. The group. The power is common or the common of	cting a false of tall sample so the group. The somputed. alculated. Ri RU > 1. to each group bVi = σ / μi.	null hypothize shown by value on earthe first row = \mu i / \mu c.	esis for this conceived the ground the groun	omparison ups is equ sents the c, the conf	n. This power all to the relative trol group

Multi-Arm Superiority by a Margin Tests for the Ratio of Treatment and Control Means (Normal Data)

Summary Statements

A parallel, 4-group design (with one control group and 3 treatment groups) will be used to test whether the mean for each treatment group is superior to the control group mean by a margin, with a superiority ratio limit of 1.25 (H0: $R \le 1.25$ versus H1: R > 1.25, $R = \mu i / \mu c$). In this study, higher means are considered to be better. The superiority-by-a-margin hypotheses will be evaluated using 3 one-sided, two-sample, Bonferroni-adjusted, equal-variance, ratio-based t-tests, with an overall (experiment-wise) Type I error rate (α) of 0.025. The common standard deviation for all groups is assumed to be 2. The control group mean is assumed to be 9.3. To detect the treatment means 12.2, 12.4, and 12.6 with at least 80% power for each test, the control group sample size needed will be 419 and the number of needed subjects for the treatment groups will be 242, 242, and 242 (totaling 1145 subjects overall).

Dropout-Inflated Sample Size

Group	Dropout Rate	Sample Size Ni	Dropout- Inflated Enrollment Sample Size Ni'	Expected Number of Dropouts Di
1	20%	419	524	105
2	20%	242	303	61
3	20%	242	303	61
4	20%	242	303	61
Total		1145	1433	288
1	20%	653	817	164
2	20%	377	472	95
3	20%	377	472	95
4	20%	377	472	95
Total		1784	2233	449
1	20%	940	1175	235
2	20%	543	679	136
3	20%	543	679	136
4	20%	543	679	136
Total		2569	3212	643

Group	Lists the group numbers.
Dropout Rate	The percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e., will be treated as "missing"). Abbreviated as DR.
Ni	The evaluable sample size for each group at which power is computed (as entered by the user). If Ni subjects are evaluated out of the Ni' subjects that are enrolled in the study, the design will achieve the stated power.
Ni'	The number of subjects that should be enrolled in each group in order to obtain Ni evaluable subjects, based
	on the assumed dropout rate. Ni' is calculated by inflating Ni using the formula Ni' = Ni / (1 - DR), with Ni'
	always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C., Shao, J., Wang, H., and
	Lokhnygina, Y. (2018) pages 32-33.)
Di	The expected number of dropouts in each group. Di = Ni' - Ni.

Dropout Summary Statements

Anticipating a 20% dropout rate, group sizes of 524, 303, 303, and 303 subjects should be enrolled to obtain final group sample sizes of 419, 242, 242, and 242 subjects.

Multi-Arm Superiority by a Margin Tests for the Ratio of Treatment and Control Means (Normal Data)

References

Blackwelder, W.C. 1998. 'Equivalence Trials.' In Encyclopedia of Biostatistics, John Wiley and Sons. New York. Volume 2, 1367-1372.

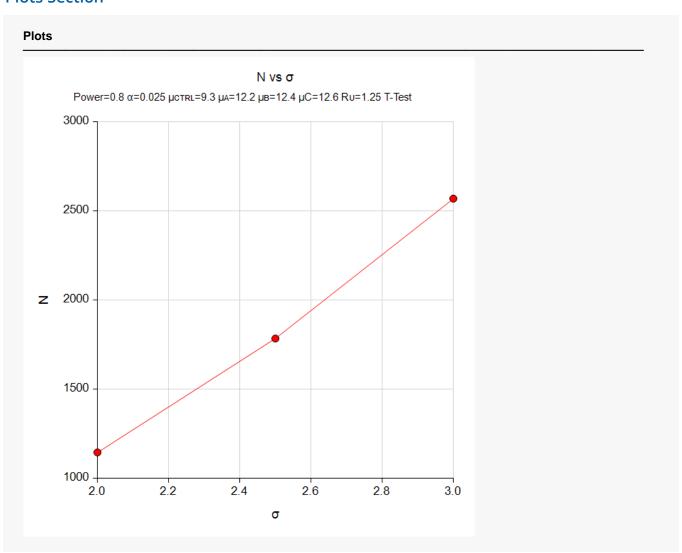
Chow, S.C., Shao, J., Wang, H., and Lokhnygina, Y. 2018. Sample Size Calculations in Clinical Research, 3rd Edition. Chapman & Hall/CRC. Boca Raton, FL. Pages 86-88.

Julious, Steven A. 2004. 'Tutorial in Biostatistics. Sample sizes for clinical trials with Normal data.' Statistics in Medicine, 23:1921-1986.

Machin, D., Campbell, M.J., Tan, S.B, and Tan, S.H. 2018. Sample Sizes for Clinical, Laboratory, and Epidemiology Studies, 4th Edition. Wiley Blackwell.

This report shows the numeric results of this power study. Notice that the results are shown in blocks of three rows at a time. Each block represents a single design.

Plots Section



This plot gives a visual presentation to the results in the Numeric Report. We can quickly see the impact on the sample size of changing the standard deviation.

Multi-Arm Superiority by a Margin Tests for the Ratio of Treatment and Control Means (Normal Data)

Example 2 – Validation using a Previously Validated Procedure

We could not find a validation result in the statistical literature, so we will use the previously validated **PASS** procedure **Superiority by a Margin Tests for the Ratio of Two Means (Normal Data)** to produce the results for the following example.

A parallel-group clinical trial is being designed to compare three treatment therapies against the standard therapy. Higher values of the response are desirable. Suppose the standard therapy has a mean response of 9.3 with a standard deviation of 2.5. The investigators would like a sample size large enough to find statistical significance at the 0.025/3 = 0.0083333 level (since this a one-sided test) if the actual mean responses of the three treatments are 12.2, 12.4, and 12.6, so the values of R1 are 1.31183, 1.33333, and 1.35484. The power of each test is 0.80 and the superiority limit is 1.25. The standard deviation is 2.5 so the COV is 0.26882.

The sample sizes of all groups will be equal.

The **Superiority by a Margin Tests for the Ratio of Two Means (Normal Data)** procedure is set up as follows.

Solve For	Power
Higher Means Are	Better (H1: R > Ru, where Ru > 1)
Alpha	0.00833 (which is Alpha / k)
Group Allocation	Equal (N1 = N2)
Sample Size Per Group	508
Test Statistic	Equal Variances T-Test
Ru (Upper Superiority Limit)	1.25
R1 (Actual Mean Ratio, µ1 / µ2)	1.31183 1.33333 1.35484
CV (Coef of Variation, σ2 / μ2)	0.26882

This set of options generates the following report.

Solve For: Groups: Ratio: Higher Me Hypothese Test:	ans Are:	R = µ1 Better H0: R :	eatment, 2 / µ2	H1: R > Ru				
				Mean R	Ratio			
	s	Sample S	lize	Upper Superiority Limit	Actual	Control Group Coefficient of Variation	Standard Deviation	
Power	N1	N2	N	Ru	Actual R1	of Variation CV	Ratio λ	Alpha
0.80059	508	508	1016	1.25	1.31183	0.26882	1	0.00833
0.97548	508	508	1016	1.25	1.33333	0.26882	1	0.00833
0.99901	508	508	1016	1.25	1.35484	0.26882	1	0.00833

A sample size of 508 in all groups will maintain a power of at least 80% for all three tests. This table contains the validation values. We will now run these values through the current procedure and compare the results with these values.

Multi-Arm Superiority by a Margin Tests for the Ratio of Treatment and Control Means (Normal Data)

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 2** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Solve For	Sample Size
Higher Means Are	Better (H1: R > RU)
Power of Each Test	0.8
Overall Alpha	0.025
Bonferroni Adjustment	Standard Bonferroni
Group Allocation	Equal (Nc = N1 = N2 =)
RU (Upper Superiority Limit)	1.25
Control Mean	9.3
Set A Number of Groups	1
Set A Mean	12.2
Set B Number of Groups	1
Set B Mean	12.4
Set C Number of Groups	1
Set C Mean	12.6
Set D Number of Groups	0
More	Unchecked
σ (Standard Deviation)	2.5

Output

Click the Calculate button to perform the calculations and generate the following output.

Solve For:		Sample Siz	е							
Group Allocation	on:	Equal (Nc =	N1 = N2 = .)						
Test Type:		Equal-Varia	nce T-Test	•						
Higher Means	Are:	Better								
Hypotheses:		H0: R ≤ RU	vs. H1: R	> RU						
Number of Gro	ups:	4								
Bonferroni Adj	ustment:	Standard B	onferroni (Di	visor = 3)						
	_					Upper			-	Alpha
	P	ower	Sample	Mean	Mean Ratio	Superiority	Standard Deviation	Coefficient of Variation		<u> </u>
Comparison	Pe Target	ower Actual	Sample Size Ni	Mean µi	Mean Ratio Ri		Standard Deviation σ	Coefficient of Variation COVi	Overall	Alpha Bonferroni- Adjusted
			Size		Ratio	Superiority Limit	Deviation	of Variation		Bonferroni-
Comparison Control vs A			Size Ni	μi	Ratio	Superiority Limit	Deviation σ	of Variation COVi		Bonferroni-
Control	Target	Actual	Size Ni 508	μi 9.3	Ratio Ri	Superiority Limit RU	Deviation σ 2.5	of Variation COVi	Overall	Bonferroni- Adjusted
Control vs A	Target	Actual 0.80061	Size Ni 508 508	9.3 12.2	Ratio Ri 1.31183	Superiority Limit RU	Deviation σ 2.5 2.5	of Variation COVi 0.26882 0.20492	Overall 0.025	Bonferroni- Adjusted

As you can see, the power values match to within rounding. The procedure is validated.