



**RACE 616 Advance Statistical Analysis in
Medical Research**

Survival Analysis

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Part II

Sample size estimation for time to event outcome

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Sample size estimation

Test for difference

$$H_0: \text{Median}_1 = \text{Median}_2 = \text{Median}_3 = \dots = \text{Median}_k$$

$$H_a: \text{Median}_1 \neq \text{Median}_2 \neq \text{Median}_3 \neq \dots \neq \text{Median}_k$$

Or

$$H_0: \text{HR}_1 = \text{HR}_2 = \text{HR}_3 = \dots = \text{HR}_k = 1$$

$$H_a: \text{HR}_1 \neq \text{HR}_2 \neq \text{HR}_3 \neq \dots \neq \text{HR}_k \neq 1$$

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Requirement of basic information

- Median survival/disease-free time for
 - Control (reference) group
 - Treatment group/s that investigator needs to detect OR
- Hazard ratio/s that investigator needs to detect
- Possible loss to follow-up rate in that setting
- Setting alpha, beta, ratio

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Software

- PS can perform only 2 groups
- STATA can perform 2-6 groups
 - artsurv (via artmenu)

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- Ex1. As for AIDS defining illness, suppose that investigators wish to conduct the study with 5-year period. The recruitment period is ~ 1 year and the follow-up time ranges from 4 - 5 years. The primary outcome of interest is time to death. The research question is whether median survival time between PCP and Tbc groups are different. Previous study provided information that median survival time of PCP was ~ 24 months. How large a sample size should investigator expect to enrol to detect difference at least 6 months.

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Set

- $\alpha = 0.05$
- $\text{Beta} = 0.8$
- Ratio 1:1
- Median
 - $Tbc \sim 18$
 - $HR = \text{Median}(Tb) / \text{Median}(PCP) = 0.75$
- Numbers of period = 5
- Time unit = 1 year
- Patient recruitment period (Accrual time) = 1 year

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Median survival time

Power and Sample Size Program: Main Window

File Log Help

Survival t-test Regression 1 Regression 2 Dichotomous Log

[Studies that are analysed by log-rank tests](#)

Output

[What do you want to know?](#) Sample size

Sample Size 214

Design


[How is the alternative hypothesis expressed?](#) two survival times

Input

α	.05	A	12	Calculate	
power	.8	m_1	24		Graphs
		m_2	18	F	
				m	1

Logging is enabled. Exit

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Base on HR

Power and Sample Size Program: Main Window

File Log Help

Survival | t-test | Regression 1 | Regression 2 | Dichotomous | Log

Studies that are analysed by log-rank tests

Output

[What do you want to know?](#) | Sample size |

[Sample Size](#) |

Design


[How is the alternative hypothesis expressed?](#) | hazard ratio or relative risk |

Input

α	<input type="text" value=".05"/>	R	<input type="text" value="0.75"/>	A	<input type="text" value="12"/>	<input type="button" value="Calculate"/> <input type="button" value="Graphs"/>
$power$	<input type="text" value=".8"/>	m_1	<input type="text" value="24"/>	F	<input type="text" value="60"/>	
				m	<input type="text" value="1"/>	

Logging is enabled.

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More than 2 groups

- Additional one more group is interested, i.e., Cryptococcal meningitis group. Median survival time of this group is at least ~ 8 months shorter than PCP group. The incidence of Crypto is ~ 2 times higher than the PCP.
- Artsurv in STATA

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artmenu on Panel 1

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Panel 2 group 1

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Panel 2 group 2

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Panel 2 group 3

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Panel 3

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ART - ANALYSIS OF RESOURCES FOR TRIALS (version 1.0.7, 19 October 2009)

A sample size program by Abdel Babiker, Patrick Royston & Friederike Barthel, MRC Clinical Trials Unit, London NW1 2DA, UK.

```

-----
Type of trial                               Superiority - time-to-event outcome
Statistical test assumed                    Unweighted logrank test (local)
Number of groups                            3
Allocation ratio                            Equal group sizes
Global test

Total number of periods                     6
Length of each period                       One year

Baseline median survival time               2 years
Survival probs per period (group 1)        0.707 0.500 0.354 0.250 0.177 0.125
Survival probs per period (group 2)        0.631 0.398 0.251 0.158 0.100 0.063
Survival probs per period (group 3)        0.595 0.354 0.210 0.125 0.074 0.044
Number of recruitment periods               1
Number of follow-up periods                 5
Method of accrual                           Uniform
Recruitment period-weights                 1 0 0 0 0 0

Hazard ratios as entered (groups 1,2,3)    1, 1.33, 1.5
Alpha                                       0.050 (two-sided)
Power (designed)                           0.800

Total sample size (calculated)              377
Expected total number of events            341
-----

```

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Tbc is ~ 3 times more prevalent than PCP,
ratio PCP:Tbc: Cryp=1:3:1

Stata/MP 11.1 - C:\New\ACTIVITY\Teaching\MD.PhD\Module2009\RACE 618\Assignments\Paper\Phisit\ACEI 27-09-2010 exclude De Galan.dta

File Edit Data Graphics Statistics User Window Help

Review

Command

```

12 artsurv, method() nperiod(5) ngr...
13 disp 24/18
14 disp 18/24
15 artsurv, method() nperiod(5) ngr...
16 artsurv, method() nperiod(5) ngr...
17 artsurv, method() nperiod(5) ngr...
18 artsurv, method() nperiod(5) ngr...
19 artsurv, method() nperiod(4) ngr...
20 artsurv, method() nperiod(5) ngr...
21 artsurv, method() nperiod(5) ngr...
22 artsurv, method() nperiod(5) ngr...
23 help artmenu
24 disp 1/1.33
25 disp 2/1.5
26 artsurv, method() nperiod(5) ngr...
27 artsurv, method() nperiod(5) ngr...
28 artsurv, method() nperiod(5) ngr...
29 artsurv, method() nperiod(5) ngr...
30 artsurv, method() nperiod(5) ngr...
31 disp 579/4

```

Variables

Name	Label	Type
meanalb		float
tcase		float
tcontrol		float
a_n		float
b_n		float
d_n		float
c_n		float
d_n		float
logRR		float
selogRR		float
lnr_micro...		float
se_micro_...		float
lnr_macro...		float
se_macro...		float

ART - ANALYSIS OF RESOURCES FOR TRIALS - Survival outcomes

Panel 1 Panel 2 Panel 3 Advanced options

Required treatment arm set-up

Choose treatment group:

Group 1 (required)

Group 2 (required)

Group 3

Group 4

Group 5

Hazard ratios

Enter relative to the control distribution

Group 2 1.33

Allocation ratio

Default: equal allocation for all groups

Group 2 3

Dose

Group 2

Trend

OK Cancel Submit

```

Hazard ratios as entered (groups 1,2) 1, 1.33
Alpha 0.050 (two-sided)
Power (designed) 0.800
Total sample size (calculated) 579
Expected total number of events 533

```

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ART - ANALYSIS OF RESOURCES FOR TRIALS (version 1.0.7, 19 October 2009)

A sample size program by Abdel Babiker, Patrick Royston & Friederike Barthel,
MRC Clinical Trials Unit, London NW1 2DA, UK.

```

-----
Type of trial Superiority - time-to-event outcome
Statistical test assumed Unweighted logrank test (local)
Number of groups 3
Allocation ratio 1.00:3.00:1.00
Global test

Total number of periods 6
Length of each period One year

Baseline median survival time 2 years
Survival probs per period (group 1) 0.707 0.500 0.354 0.250 0.177 0.125
Survival probs per period (group 2) 0.631 0.398 0.251 0.158 0.100 0.063
Survival probs per period (group 3) 0.595 0.354 0.210 0.125 0.074 0.044
Number of recruitment periods 1
Number of follow-up periods 5
Method of accrual Uniform
Recruitment period-weights 1 0 0 0 0

Hazard ratios as entered (groups 1,2,3) 1, 1.33, 1.5
Alpha 0.050 (two-sided)
Power (designed) 0.800

Total sample size (calculated) 608
Expected total number of events 553
-----

```

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Allocation ratio 1:2:2

ART - ANALYSIS OF RESOURCES FOR TRIALS - Survival outcomes

Required treatment arm set-up

Choose treatment group:

- Group 1 (required)
- Group 2 (required)
- Group 3
- Group 4
- Group 5

Hazard ratios: Enter relative to the control distribution

Group 2: 1.33

Allocation ratio: Default: equal allocation for all groups

Group 2: 2

Dose: Group 2

Number of recruitment periods: 1

Number of follow-up periods: 4

Method of accrual: Uniform

Recruitment period-weights: 1 0 0 0

Hazard ratios as entered (groups 1,2,3): 1, 1.33, 1.5

Hazard ratios per period (group 1): 1.000 1.000 1.000 1.000 1.000

Hazard ratios per period (group 2): 1.330 1.330 1.330 1.330 1.330

Hazard ratios per period (group 3): 1.500 1.500 1.500 1.500 1.500

Alpha: 0.050 (two-sided)

Power (designed): 0.800

Total sample size (calculated): 550

Expected total number of events: 163

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ART - ANALYSIS OF RESOURCES FOR TRIALS - Survival outcomes

Required treatment arm set-up

Choose treatment group:

- Group 1 (required)
- Group 2 (required)
- Group 3
- Group 4
- Group 5

Hazard ratios: Enter relative to the control distribution

Group 3: 1.5

Allocation ratio: Default: equal allocation for all groups

Group 3: 2

Dose: Group 3

Number of recruitment periods: 1

Number of follow-up periods: 4

Method of accrual: Uniform

Recruitment period-weights: 1 0 0 0

Hazard ratios as entered (groups 1,2,3): 1, 1.33, 1.5

Hazard ratios per period (group 1): 1.000 1.000 1.000 1.000 1.000

Hazard ratios per period (group 2): 1.330 1.330 1.330 1.330 1.330


Hazard ratios per period (group 3): 1.500 1.500 1.500 1.500 1.500

Alpha: 0.050 (two-sided)

Power (designed): 0.800

Total sample size (calculated): 550

Expected total number of events: 163



ART - ANALYSIS OF RESOURCES FOR TRIALS (version 1.0.7, 19 October 2009)

A sample size program by Abdel Babiker, Patrick Royston & Friederike Barthel, MRC Clinical Trials Unit, London NW1 2DA, UK.

Type of trial Superiority - time-to-event outcome
 Statistical test assumed Unweighted logrank test (local)
 Number of groups 3
 Allocation ratio 1.00:2.00:2.00
 Global test


Total number of periods 6
 Length of each period One year

Baseline median survival time 2 years
 Survival probs per period (group 1) 0.707 0.500 0.354 0.250 0.177 0.125
 Survival probs per period (group 2) 0.631 0.398 0.251 0.158 0.100 0.063
 Survival probs per period (group 3) 0.595 0.354 0.210 0.125 0.074 0.044
 Number of recruitment periods 1
 Number of follow-up periods 5
 Method of accrual Uniform
 Recruitment period-weights 1 0 0 0 0

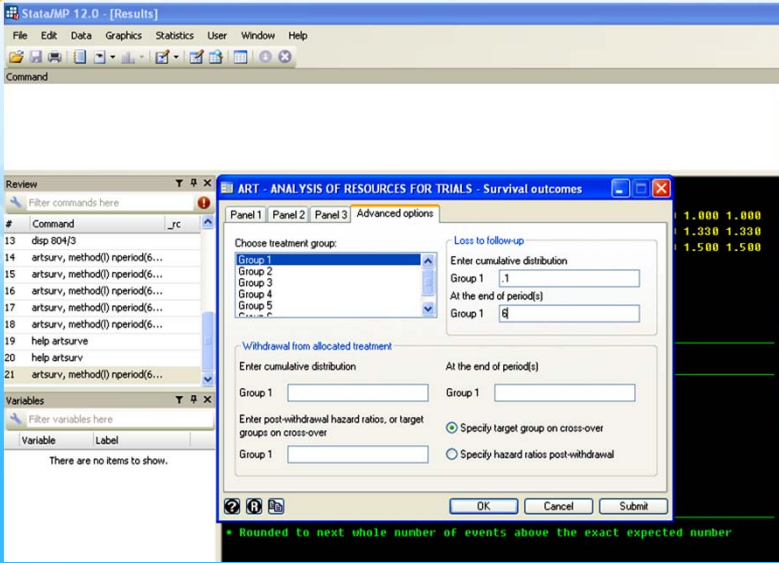
Hazard ratios as entered (groups 1,2,3) 1, 1.33, 1.5
 Alpha 0.050 (two-sided)
 Power (designed) 0.800

Total sample size (calculated) 499
 Expected total number of events 457

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Group 1,2,3: loss to FU



Stata/MP 12.0 - [Results]

File Edit Data Graphics Statistics User Window Help

Command

Review

Filter commands here

Command _rc

13 dsp 804/3

14 artsurv, method() nperiod(6...

15 artsurv, method() nperiod(6...

16 artsurv, method() nperiod(6...

17 artsurv, method() nperiod(6...

18 artsurv, method() nperiod(6...

19 help artsurv

20 help artsurv

21 artsurv, method() nperiod(6...

Variables

Filter variables here

Variable Label

There are no items to show.

ART - ANALYSIS OF RESOURCES FOR TRIALS - Survival outcomes

Panel 1 Panel 2 Panel 3 Advanced options

Choose treatment group:

Group 1
 Group 2
 Group 3
 Group 4
 Group 5

Loss to follow-up

Enter cumulative distribution
 Group 1 .1
 At the end of period(s)
 Group 1 1

Withdrawal from allocated treatment

Enter cumulative distribution
 Group 1
 At the end of period(s)
 Group 1

Enter post-withdrawal hazard ratios, or target groups on cross-over

Specify target group on cross-over
 Specify hazard ratios post-withdrawal

Group 1

OK Cancel Submit

* Rounded to next whole number of events above the exact expected number

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Group 2

Stata/MP 12.0 - [Results]

File Edit Data Graphics Statistics User Window Help

Command

Review

Filter commands here

#	Command	_rc
13	disp 804/3	
14	artsurv, method() nperiod(6...	
15	artsurv, method() nperiod(6...	
16	artsurv, method() nperiod(6...	
17	artsurv, method() nperiod(6...	
18	artsurv, method() nperiod(6...	
19	help artsurv	
20	help artsurv	
21	artsurv, method() nperiod(6...	

Variables

Filter variables here

Variable	Label
There are no items to show.	

ART - ANALYSIS OF RESOURCES FOR TRIALS - Survival outcomes

Panel 1 Panel 2 Panel 3 Advanced options

Choose treatment group:

- Group 1
- Group 2
- Group 3
- Group 4
- Group 5
- Group 6

Loss to follow-up

Enter cumulative distribution

Group 2 1

At the end of period(s)

Group 2 6

Withdrawal from allocated treatment

Enter cumulative distribution

Group 2

At the end of period(s)

Group 2

Enter post-withdrawal hazard ratios, or target groups on cross-over

Group 2

Specify target group on cross-over

Specify hazard ratios post-withdrawal

OK Cancel Submit

* Rounded to next whole number of events above the exact expected number

1.000 1.000
1.330 1.330
1.500 1.500

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Group 3

Stata/MP 12.0 - [Results]

File Edit Data Graphics Statistics User Window Help

Command

Review

Filter commands here

#	Command	_rc
13	disp 804/3	
14	artsurv, method() nperiod(6...	
15	artsurv, method() nperiod(6...	
16	artsurv, method() nperiod(6...	
17	artsurv, method() nperiod(6...	
18	artsurv, method() nperiod(6...	
19	help artsurv	
20	help artsurv	
21	artsurv, method() nperiod(6...	

Variables

Filter variables here

Variable	Label
There are no items to show.	

ART - ANALYSIS OF RESOURCES FOR TRIALS - Survival outcomes

Panel 1 Panel 2 Panel 3 Advanced options

Choose treatment group:

- Group 1
- Group 2
- Group 3
- Group 4
- Group 5
- Group 6

Loss to follow-up

Enter cumulative distribution

Group 3 1

At the end of period(s)

Group 3 6

Withdrawal from allocated treatment

Enter cumulative distribution

Group 3

At the end of period(s)

Group 3

Enter post-withdrawal hazard ratios, or target groups on cross-over

Group 3

Specify target group on cross-over

Specify hazard ratios post-withdrawal

OK Cancel Submit

Haz
Haz
Haz
01p
Pow
Tot.
Exp
Val
Unav
Unav
Exp
Exp
Exp
* R

1.000
1.330
1.500

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A sample size program by Abdel Babiker, Patrick Royston & Friederike Barthel,
MRC Clinical Trials Unit, London NW1 2DA, UK.

Type of trial	Superiority - time-to-event outcome					
Statistical test assumed	Unweighted logrank test (local)					
Number of groups	3					
Allocation ratio	1.00:2.00:2.00					
Global test						
Total number of periods	6					
Length of each period	One year					
Baseline median survival time	2 years					
Survival probs per period (group 1)	0.707	0.500	0.354	0.250	0.177	0.125
Survival probs per period (group 2)	0.631	0.398	0.251	0.158	0.100	0.063
Survival probs per period (group 3)	0.595	0.354	0.210	0.125	0.074	0.044
Number of recruitment periods	1					
Number of follow-up periods	5					
Method of accrual	Uniform					
Recruitment period-weights	1 0 0 0 0					
Hazard ratios as entered (groups 1,2,3)	1, 1.33, 1.5					
Hazard ratios per period (group 1)	1.000	1.000	1.000	1.000	1.000	1.000
Hazard ratios per period (group 2)	1.330	1.330	1.330	1.330	1.330	1.330
Hazard ratios per period (group 3)	1.500	1.500	1.500	1.500	1.500	1.500
Alpha	0.050 (two-sided)					
Power (designed)	0.800					
Total sample size (calculated)	515					
Expected total number of events	458					

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Values given below apply to each group at the end of the trial

Unadjusted event probs (groups 1,2,3)	0.875, 0.937, 0.956
Unadjusted loss to follow-up probs	0.100, 0.100, 0.100
Unadjusted cross-over probabilities	0.000, 0.000, 0.000

*Expected numbers of events per group	85, 185, 189
Expected proportions with event	0.823, 0.893, 0.916
Expected proportions lost to follow-up	0.042, 0.034, 0.031
Expected proportions with cross-over	0.000, 0.000, 0.000

* Rounded to next whole number of events above the exact expected number

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- Exercise 2. Investigators would like to conduct a randomised control trial which aim to assess recovery rates between treatments (i.e., Prednisolone and Acyclovir plus Prednisolone) in Bell's palsy patients. The primary outcome of interest is time since receiving treatment to disease recovery, which is defined as House-Brackman score ≤ 2 . Since Acyclovir is more expensive than Prednisolone, investigators thus set a ratio of 2:1 for Prednisolone versus Acyclovir. Previous studies reported that median time to disease recovery was ~ 4 -6 months for Prednisolone group. Adding Acyclovir should be able to shorten the median recovery time and it will be clinically significant if the median time to recovery can be only ~ 3 -4 months. How large is the sample size if the study period is 12 months & recruitment period is 6 months?

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- Alpha = 0.05
- Beta = 0.2
- Ratio 2:1
- Median(Pred) = 6 months
- PS: longer median time will yield larger sample size
- Median(Acy) = 3 months
- HR = $6/3 = 2$

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Panel 1

Panel 1 Panel 2 Panel 3 Advanced options

Set-up

Number of periods: 12
 Number of groups: 2
 Time unit (= 1 period): Month
 Alpha (2-sided): 0.05
 Median survival time: 6
 Power or N: 0.8
 Baseline survival or failure probabilities: .5
 At the end of period(s): 6

Options

Specify power Specify sample size
 Specify baseline survival probabilities Specify baseline failure probabilities
 Noninferiority design One-sided alpha

OK Cancel Submit

```

number of recruitment periods      1
number of follow-up periods      11
method of accrual                  uniform
recruitment period-weights
1 0 0 0 0 0 0 0 0 0 0 0
Hazard ratios as entered (groups 1,2)
1, 2
Hazard ratios per period (group 1)
1.000 1.000 1.000 1.000 1.000 1.000
Hazard ratios per period (group 2)
2.000 2.000 2.000 2.000 2.000 2.000
Alpha (designed)
0.050 (two-sided)
power
0.800
Total sample size (calculated)    94
expected total number of events   67
more
    
```

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Panel 2 group 1

Panel 1 Panel 2 Panel 3 Advanced options

Required treatment arm set-up

Choose treatment group:

- Group 1 (required)
- Group 2 (required)
- Group 3
- Group 4
- Group 5

Hazard ratios

Enter relative to the control distribution

Group 1: 1
 Group 2: 2

Allocation ratio

Default allocation for all groups

Group 1: 1
 Group 2: 2

Dose

Group 1: []

Trend

OK Cancel Submit

```

Total sample size (calculated)    94
expected total number of events   67
values given below apply to each group at the end of the trial
unadjusted event probs (groups 1,2) 0.646, 0.875
unadjusted loss to follow-up probs 0.000, 0.000
unadjusted crossover probabilities 0.000, 0.000
Expected proportions with event      0.631, 0.864
Expected proportions lost to follow-up 0.000, 0.000
Expected proportions with crossover 0.000, 0.000
    
```

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Panel 2 group 2

Required treatment arm set-up

Choose treatment group:

- Group 1 (required)
- Group 2 (required)
- Group 3
- Group 4
- Group 5

Hazard ratios

Enter relative to the control distribution

Group 2: 2

Allocation ratio

Default: equal allocation for all groups

Group 2: 2

OK Cancel Submit

Total sample size (calculated) 94
 Expected total number of events 67

values given below apply to each group at the end of the trial

unadjusted event probs (groups 1,2)	0.646	0.875
unadjusted loss to follow-up probs	0.000	0.000
unadjusted crossover probabilities	0.000	0.000
Expected proportions with event	0.631	0.864
Expected proportions lost to follow-up	0.000	0.000
Expected proportions with crossover	0.000	0.000

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Panel 3

Patient recruitment

Duration: 6 Proportion recruited at start: 0

Equal weights over periods (selected) Uniform accrual (selected)

Unequal weights: Exponential accrual:

Model Options

Local alternatives (selected) Distant alternatives


Method of sample size calculation: logrank, unweighted

Additional details in output (checked) Save using filename:

OK Cancel Submit

1.000	1.000
1.330	1.330
1.500	1.500

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ART - ANALYSIS OF RESOURCES FOR TRIALS (version 1.0.7, 19 October 2009)

A sample size program by Abdel Babiker, Patrick Royston & Friederike Barthel, MRC Clinical Trials Unit, London NW1 2DA, UK.

Type of trial	Superiority - time-to-event outcome
Statistical test assumed	Unweighted logrank test (local)
Number of groups	2
Allocation ratio	1.00:2.00


Total number of periods	12
Length of each period	One month

Baseline median survival time	6 months
Survival probs per period (group 1)	0.891 0.794 0.707 0.630 0.561 0.500 0.445 0.397 0.354 0.315 0.281 0.250
Survival probs per period (group 2)	0.794 0.630 0.500 0.397 0.315 0.250 0.198 0.157 0.125 0.099 0.079 0.062
Number of recruitment periods	6
Number of follow-up periods	6
Method of accrual	Uniform
Recruitment period-weights	1 1 1 1 1 0 0 0 0 0

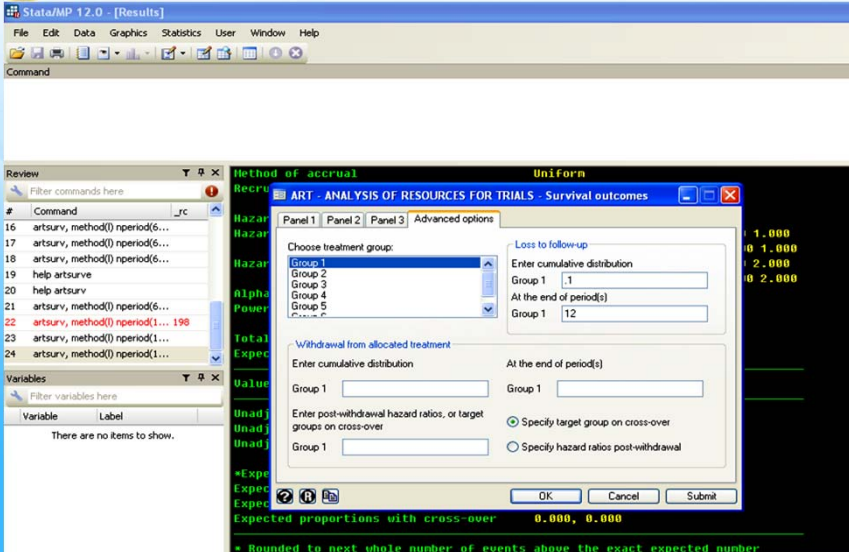
Hazard ratios as entered (groups 1,2)	1, 2
Hazard ratios per period (group 1)	1.000 1.000 1.000 1.000 1.000 1.000 1.000 1.000 1.000 1.000 1.000 1.000
Hazard ratios per period (group 2)	2.000 2.000 2.000 2.000 2.000 2.000 2.000 2.000 2.000 2.000 2.000 2.000
Alpha	0.050 (two-sided)
Power (designed)	0.800

Total sample size (calculated)	103
Expected total number of events	82

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Advance option: lost FU 10% group 1



StataMP 12.0 - [Results]

Method of accrual: Uniform

ART - ANALYSIS OF RESOURCES FOR TRIALS - Survival outcomes

Panel 1 | Panel 2 | Panel 3 | Advanced options

Choose treatment group: Group 1 (selected)

Loss to follow-up

Enter cumulative distribution

Group 1: .1

At the end of period(s)

Group 1: 12

Withdrawal from allocated treatment

Enter cumulative distribution

Group 1: []

At the end of period(s)

Group 1: []

Enter post-withdrawal hazard ratios, or target groups on cross-over

Group 1: []

Specify target group on cross-over

Specify hazard ratios post-withdrawal

OK Cancel Submit

Expected proportions with cross-over: 0.000, 0.000

* Rounded to next whole number of events above the exact expected number

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Group 2

Method of accrual Uniform

ART - ANALYSIS OF RESOURCES FOR TRIALS - Survival outcomes

Choose treatment group:
Group 1
Group 2
Group 3
Group 4
Group 5

Loss to follow-up
Enter cumulative distribution
Group 2 | 1
At the end of period(s)
Group 2 | 12

Withdrawal from allocated treatment
Enter cumulative distribution
At the end of period(s)
Group 2 |
Group 2 |

Enter post-withdrawal hazard ratios, or target groups on cross-over
 Specify target group on cross-over
 Specify hazard ratios post-withdrawal
Group 2 |
Group 2 |

Expected proportions with cross-over: 0.000, 0.000

* Rounded to next whole number of events above the exact expected number

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ART - ANALYSIS OF RESOURCES FOR TRIALS (version 1.0.7, 19 October 2009)

A sample size program by Abdel Babiker, Patrick Royston & Friederike Barthel, MRC Clinical Trials Unit, London NW1 2DA, UK.

Type of trial	Superiority - time-to-event outcome
Statistical test assumed	Unweighted logrank test (local)
Number of groups	2
Allocation ratio	1.00:2.00
Total number of periods	12
Length of each period	One month
Baseline median survival time	6 months
Survival probs per period (group 1)	0.891 0.794 0.707 0.630 0.561 0.500 0.445 0.397 0.354 0.315 0.281 0.250
Survival probs per period (group 2)	0.794 0.630 0.500 0.397 0.315 0.250 0.198 0.157 0.125 0.099 0.079 0.062
Number of recruitment periods	6
Number of follow-up periods	6
Method of accrual	Uniform
Recruitment period-weights	1 1 1 1 1 0 0 0 0 0
Hazard ratios as entered (groups 1,2)	1, 2
Hazard ratios per period (group 1)	1.000 1.000 1.000 1.000 1.000 1.000 1.000 1.000 1.000 1.000 1.000 1.000
Hazard ratios per period (group 2)	2.000 2.000 2.000 2.000 2.000 2.000 2.000 2.000 2.000 2.000 2.000 2.000
Alpha	0.050 (two-sided)
Power (designed)	0.800
Total sample size (calculated)	107
Expected total number of events	82

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 Values given below apply to each group at the end of the trial

Unadjusted event probs (groups 1,2)	0.750, 0.938
Unadjusted loss to follow-up probs	0.100, 0.100
Unadjusted cross-over probabilities	0.000, 0.000

*Expected numbers of events per group	23, 61
Expected proportions with event	0.619, 0.842
Expected proportions lost to follow-up	0.047, 0.032
Expected proportions with cross-over	0.000, 0.000

 * Rounded to next whole number of events above the exact expected number

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