

· 专题研究 ·

# 样本量估计及其在 nQuery 和 SAS 软件上的实现 ——均数比较(五)

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### 1.2.1.8 2 × 2 交叉设计

方法: Senn (2002)<sup>[11]</sup> 给出的 2 × 2 交叉设计的样本量估计方法是建立在自由度为 2(n-1), 非中心参数为  $\sqrt{n} \left( \frac{\mu_1 - \mu_2}{\sigma_d \cdot \sqrt{2}} \right)$  的非中心 t 分布上, 其检验效能的计算公式为:

$$1 - \beta = 1 - \text{Probt} \left( t_{1-\alpha/s, n-2}, 2(n-1), \sqrt{n} \left( \frac{\mu_1 - \mu_2}{\sigma_d \cdot \sqrt{2}} \right) \right) \quad (1-15)$$

式中,  $\mu_1, \mu_2$  分别为两阶段均数,  $\sigma_d = \frac{\sqrt{MSE}}{\sqrt{2}}$ , MSE 是方差分析的均方差。

在计算样本量时, 一般先设定样本量初始值, 然后迭代样本量直到所得的检验效能满足条件为止。此时的样本量, 即研究所需的样本量。

【例 1-14】某临床试验欲评价某款血液灌流器对终末期肾病患者的临床疗效, 采用基础干预作为对照, 以  $\beta_2$ -MG 下降率为主要评价指标。依据预试验结果, 试验组的  $\beta_2$ -MG 下降率为 30% ± 15% ( $\bar{x} \pm s$ ), 试验组的  $\beta_2$ -MG 下降率与对照组之差的总体均数为 20%, 二阶段交叉设计方差分析的标准误为 10%, 相应地阶段之间差值的总体均数为 0%, 标准差为 14.142%。试估计检验效能为 95% 时的样本量。

nQuery Advisor 7.0 实现:

设定检验水准  $\alpha = 0.05$ , 双侧检验, 即  $s = 2$ ; 检验效能取  $1 - \beta = 95\%$ 。由题意知,  $\mu_1 = 0.3, \mu_2 = 0.1, \sigma = 0.15$ 。

在 nQuery Advisor 7.0 主菜单选择:

Goal: Make Conclusion Using:  Means

Number of Groups:  Two

Analysis Method:  Test

方法框中选择: 2 × 2 Crossover Design。

在弹出的样本量计算窗口将各参数键入, 如图 1-35 所示, 结果为  $n = 5$ 。

SAS 9.2 软件实现:

t-test (ANOVA) for difference of means in 2 x 2 crossover design			
	1	2	3
Test significance level, $\alpha$	0.050		
1 or 2 sided test?	2		
Placebo mean, $\mu_1$	0.300		
New therapy mean, $\mu_2$	0.100		
Difference in means, $\mu_1 - \mu_2$	0.200		
Crossover ANOVA sqrt(MSE)	0.100		
Standard deviation of differences, $\sigma_d$	0.150		
Power (%)	95		
n per sequence group	5		

图 1-35 nQuery Advisor 7.0 关于例 1-14 样本量估计的参数设置与计算结果

```

PROC IML;
start MTT4(a, s, mean1, mean2, ca, power);
error = 0;
if(a > 1 | a < 0) then do; error = 1; print "error"
"Test significance level must be in 0-1"; end;
if(s = 1 & s = 2) then do; error = 1; print "error"
"s = 1 or 2"; end;
if(ca <= 0) then do; error = 1; print "error"
"Crossover ANOVA sqrt(MSE) must be >0"; end;
if(power > 100 | power < 1) then do; error = 1;
print "error" "Power(%) must be in 1-100"; end;
if(error = 1) then stop;
if(error = 0) then do; sd = sqrt(2)#ca;
es = 2 * abs(mean1 - mean2)/sd; n = 2;
do until(pw >= power/100);
ncp = sqrt(n)#es/sqrt(2); df = 2#(n-1);
t = tinv(1-a/s, df); pw = 1-probt(t, df, ncp);
n = n + 0.01; end;
n = ceil(n-0.01);
print a[ label = "Test Significance level" ]
s[ label = "1 or 2 sided test" ]
mean1[ label = "Placebo mean" ]
mean2[ label = "New therapy mean" ]
ca[ label = "Crossover ANOVA sqrt( MSE )" ]
sd[ label = "Standard deviation of difference" ]
power[ label = "Power( % )" ]
n[ label = "n" ]; end;
finish MTT4;
run MTT4(0.05, 2, 0.3, 0.1, 0.106, 95); quit;
SAS 运行结果:

```

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Test Significance level	1 or 2 sided test	Placebo mean	New therapy mean	Crossover ANOVA sqrt(MSE)	Standard deviation of difference	Power (%)	n
0.05	2	0.3	0.1	0.106	0.1499066	95	5

图 1-36 SAS 9.2 关于例 1-14 样本量估计的参数设置与计算结果

1.2.2 等效性检验

1.2.2.1 两均数比较的等效性检验

方法: Dixon 和 Massey (1983)<sup>[2,3]</sup> 等给出两均数比较的等效性检验的样本量估计是建立在自由度为 2(n-1), 非中心参数为  $\sqrt{n}|\Delta_1 - \Delta_0|/(\sqrt{2}\sigma)$  的非中心 t 分布上, 其检验效能的计算公式为:

$$1 - \beta = 1 - \text{Probt}(t_{1-\alpha, 2(n-1)}, 2(n-1), \sqrt{n}|\Delta_1 - \Delta_0|/(\sqrt{2}\sigma)) \quad (1-16)$$

式中,  $\Delta_1$  代表期望的差值,  $\Delta_0$  代表等效的界值;  $\sigma$  为总体标准差。

在计算样本量时, 一般先设定样本量初始值, 然后迭代样本量直到所得的检验效能满足条件为止。此时的样本量, 即研究所需的样本量。

【例 1-15】某临床试验欲验证一种降血压的仿制药不劣于其原研药。据以往研究数据, 原研药在为期四周的治疗后平均降低舒张压 12mmHg, 相应标准差为 6mmHg。临床认可的劣界值为 1.5mmHg。若预期试验药的降压效果与原研药一样为 12mmHg, 试估计检验效能为 80% 的样本量。

nQuery Advisor 7.0 实现:

设定检验水准  $\alpha=0.025$ , 双单侧检验, 检验效能取  $1-\beta=80\%$ 。由上述基础数据可知,  $\Delta_0 = -1.5, \Delta_1 = 0, \sigma = 6$ 。

在 nQuery Advisor 7.0 主菜单选择:

Goal: Make Conclusion Using:  Means

Number of Groups:  Two

Analysis Method:  Equivalence

方法框中选择: Equivalence of two means。

在弹出的样本量计算窗口将各参数键入, 如图 1-37 所示, 结果为  $n=253$ 。

SAS 9.2 软件实现:

```
PROC IML;
start MTE0(a, eld, ed, sd, power);
error = 0;
```

```
if(a > 1 | a < 0) then do; error = 1; print "error"
"Test significance level must be in 0-1"; end;
```

Two group t-test of equivalence in means (equal n's)				
	1	2	3	4
Test significance level, $\alpha$ (one-sided)	0.025			
Equivalence limit difference, $\Delta_0$	-1.500			
Expected difference, $\Delta_1$	0.000			
$\Delta_0 - \Delta_1$	-1.500			
Common standard deviation, $\sigma$	6.000			
Effect size, $\delta =  \Delta_0 - \Delta_1 /\sigma$	0.250			
Power (%)	80			
n per group	253			

图 1-37 nQuery Advisor 7.0 关于例 1-15 样本量估计的参数设置与计算结果

```
if(sd < 0) then do; error = 1; print "error" "stand-
ard deviation must be > =0"; end;
```

```
if(power > 100 | power < 1) then do; error = 1;
print "error" "Power(%) must be in 1-100"; end;
```

```
if(error = 1) then stop;
```

```
if(error = 0) then do;
```

```
es = abs(ed-eld)/sd; n = 2;
```

```
do until(pw >= power/100);
```

```
nep = sqrt(n)#es/sqrt(2); df = 2#(n-1);
```

```
t = tinvt(1-a, df); pw = 1-probt(t, df, nep);
```

```
n = n + 0.01; end;
```

```
n = ceil(n-0.01);
```

```
print a[ label = "Test significance level"]
```

```
eld[ label = "Equivalence limit difference"]
```

```
ed[ label = "Expected difference"]
```

```
sd[ label = "Common standard deviation"]
```

```
power[ label = "Power(%)"]
```

```
n[ label = "n per group"]; end;
```

```
finish MTE0;
```

```
run MTE0(0.025, -1.5, 0, 6, 80); quit;
```

SAS 运行结果:

Test significance level	Equivalence limit difference	Expected difference	Common standard deviation	Power (%)	n per group
0.025	-1.5	0	6	80	253

图 1-38 SAS 9.2 关于例 1-15 样本量估计的参数设置与计算结果

1.2.2.2 两组设计的双单侧等效性检验

方法: 根据 Schuirmann<sup>[12]</sup>、Phillips<sup>[13]</sup>、Owen<sup>[14]</sup> 的方法, 双单侧等效性验证中使用劣侧和优侧 2 个界值,

检验效能及样本量估计是建立在非中心参数为  $\tau_1$  和  $\tau_2$  的非中心 t 分布上, 其检验效能的计算公式为:

$$1 - \beta = 1 - \text{Probt}(t_{1-\alpha, 2(n-1)}, 2(n-1), \tau_2) - \text{Probt}$$

$$(t_{1-\alpha, 2(n-1)}, 2(n-1), \tau_1) \quad (1-17)$$

式中,  $\tau_1$  和  $\tau_2$  为非中心参数

$$\tau_1 = \frac{1(\mu_T - \mu_S) - \Delta_L \sqrt{n}}{\sqrt{2\sigma^2}};$$

$$\tau_2 = \frac{1(\mu_T - \mu_S) - \Delta_U \sqrt{n}}{\sqrt{2\sigma^2}} \quad (1-18)$$

式中,  $\mu_T$  为检验组均值,  $\mu_S$  为标准组均值;  $\Delta_L$  为下界,  $\Delta_U$  为上界。

在计算样本量时,一般先设定样本量初始值,然后迭代样本量直到所得的检验效能满足条件为止。此时的样本量,即研究所需的样本量。

【例 1-16】某临床试验欲验证一种降血压的仿制药等效于其原研药。据以往研究数据,原研药在为期四周的治疗后将舒张压平均维持在 86mmHg,相应标准差为 15mmHg。假定临床上认为等效界值取原研药标准差的 25%,即 15 mmHg × 0.25 ≈ 4 mmHg。若采用平衡设计,试估计检验效能为 80% 的样本量。

nQuery Advisor 7.0 实现:

设定检验水准  $\alpha = 0.025$ , 双单侧检验, 检验效能取  $1 - \beta = 80\%$ 。依据上述基础数据可知,  $\Delta_L = -4$ ,  $\Delta_U = 4$ , 标准差  $\sigma = 15$ 。

在 nQuery Advisor 7.0 主菜单选择:

Goal: Make Conclusion Using;  Means

Number of Groups;  Two

Analysis Method;  Equivalence

方法框中选择: Two one-sided equivalence test (TOST) for two-group design。

在弹出的样本量计算窗口将各参数键入,如图 1-39 所示,结果为  $n = 297$ 。

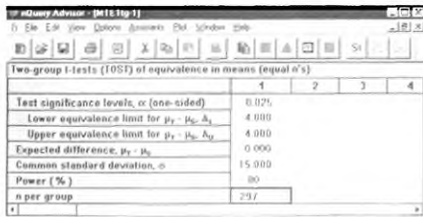


图 1-39 nQuery Advisor 7.0 关于例 1-16 样本量估计的参数设置与计算结果

SAS 9.2 软件实现:

```
proc IML;
start MTE1tg(a, Leld, Ueld, ed, sd, power);
error = 0;
if(a > 1 | a < 0) then do; error = 1; print "error"
"Test significance level must be in 0-1"; end;
if(sd < 0) then do; error = 1; print "error" "stand-
ard deviation must be > = 0"; end;
if(Leld > Ueld) then do; error = 1; print "error"
"Lower equivalence limit difference must be < = Up-
per equivalence limit difference"; end;
if(Ueld < Leld) then do; error = 1; print "error"
"Upper equivalence limit difference must be > = Low-
er equivalence limit difference"; end;
if(ed < = Leld | ed > = Ueld) then do; error = 1; print
"error" "Expected difference must be in Leld-Ueld"; end;
if(power > 100 | power < 1) then do; error = 1;
print "error" "Power(%) must be in 1-100"; end;
if(error = 1) then stop;
if(error = 0) then do; n = 2;
do until(pw1 + pw2 - 1 > = power/100);
L_ncp = abs(ed-Leld)#sqrt(n)/(sd#sqrt(2));
U_ncp = abs(ed-Ueld)#sqrt(n)/(sd#sqrt(2));
df = 2 * (n-1); t = tinv(1-a, df);
pw1 = 1-probt(t, df, L_ncp);
pw2 = 1-probt(t, df, U_ncp);
n = n + 0.01; end;
n = ceil(n-0.01);
print a[ label = "Test significance level"]
Leld [ label = "Lower equivalence limit differ-
ence"]
Ueld [ label = "Upper equivalence limit differ-
ence"]
ed[ label = "Expected difference"]
sd[ label = "Common standard deviation"]
power[ label = "Power(%)"]
n[ label = "n per group"]; end;
finish MTE1tg;
run MTE1tg(0.025, -4, 4, 0, 15, 80); quit;
```

Test significance level	Lower equivalence limit difference	Upper equivalence limit difference	Expected difference	Common standard deviation	Power (%)	n per group
0.025	-4	4	0	15	80	297

图 1-40 SAS 9.2 关于例 1-16 样本量估计的参数设置与计算结果

### 1.2.2.3 交叉设计的双单侧等效性检验

方法: 根据 Schuirmann<sup>[12]</sup>等<sup>[13-15]</sup>提出的方法, 交叉设计的等效性检验方法与两样本的等效性检验方

法一致, 检验效能及样本量估计是基于非中心参数为  $\tau_1$  和  $\tau_2$  的非中心  $t$  分布。其检验效能的计算公式为:

$$1 - \beta = 1 - \text{Probt}(t_{1-\alpha, 2(n-1)}, 2(n-1), \tau_2) - \text{Probt}$$

$$(t_{1-\alpha, 2(n-1)}, 2(n-1), \tau_1) \quad (1-19)$$

式中,  $\tau_1$  和  $\tau_2$  为非中心参数

$$\tau_1 = \frac{1(\mu_T - \mu_S) - \Delta_L \sqrt{n}}{\sqrt{2\sigma_d^2}};$$

$$\tau_2 = \frac{1(\mu_T - \mu_S) - \Delta_U \sqrt{n}}{\sqrt{2\sigma_d^2}} \quad (1-20)$$

$\mu_T$  为检验组均值,  $\mu_S$  为标准组均值;  $\Delta_L$  为下界,  $\Delta_U$  为上界;  $\sigma = \frac{\sigma_d}{2} = \sqrt{\frac{MSE}{2}}$ ;  $MSE$  是方差分析的均方差,

$MSE = \frac{\sigma_1^2 + \sigma_2^2 - 2\rho\sigma_1\sigma_2}{2}$ ,  $\sigma_1, \sigma_2$  为分别两阶段的方差,  $\rho$  为两阶段的相关系数。

在计算样本量时,一般先设定样本量初始值,然后迭代样本量直到所得的检验效能满足条件为止。此时的样本量,即研究所需的样本量。

【例 1-17】某临床试验欲验证某款血液透析器新产品(简称“试验品”)等效于某一临床普遍使用的血液透析器(简称“对照品”)。该研究的主要评价指标为尿素氮下降率。临床专家认为等效限值  $\Delta$  取 7% 为宜。根据以往对照品的数据得到标准差为 20%, 阶段之间的相关系数为 0.6。假定试验品的尿素氮下降率总体均数与对照品的尿素氮下降率总体均数相等, 试验品与对照品的总体标准差均为 20%, 试估计检验效能为 80% 时的样本量。

nQuery Advisor 7.0 实现:

设定检验水准  $\alpha = 0.025$  (双单侧), 检验效能取  $1 - \beta = 80\%$ 。由题意知,  $\Delta_L = -0.07, \Delta_U = 0.07$ 。在 nQuery Advisor 7.0 主菜单选择:

Goal: Make Conclusion Using:  Means

Number of Groups:  Two

Analysis Method:  Equivalence

方法框中选择: Two one-sided equivalence tests (TOST) for crossover design。

注意, 这里首先应根据已知数据计算标准误  $\sigma_d$ , 在菜单栏中选择:

Assistants:  Estimate SD

在弹出的标准差计算窗口将  $\sigma_1 = 0.2, \sigma_2 = 0.2, \rho = 0.6$  键入, 求得  $\sigma_d = 0.179$ , 如图 1-41 所示。

Calculating standard deviation of differences from SD1, SD2, and correlation				
	1	2	3	4
First condition standard deviation, $\sigma_1$	0.200			
Second condition standard deviation, $\sigma_2$	0.200			
Correlation coefficient, $\rho$	0.600			
Standard deviation of differences, $\sigma_d$	0.179			

图 1-41 nQuery Advisor 7.0 关于例 1-17

样本量估计的参数计算结果

将计算结果  $\sigma_d = 0.179$  和其他参数键入样本量计算窗口, 如图 1-42 所示, 结果为  $n = 36$ 。

t-tests (TOST) of equivalence in means for crossover design				
	1	2	3	4
Test significance levels, $\alpha$ (one-sided)	0.025			
Lower equivalence limit for $\mu_1 - \mu_2$ , $\Delta_L$	-0.070			
Upper equivalence limit for $\mu_1 - \mu_2$ , $\Delta_U$	0.070			
Expected difference, $\mu_1 - \mu_2$	0.000			
Crossover ANOVA $\text{sqrt}(MSE)$	0.177			
Standard deviation of differences, $\sigma_d$	0.179			
Power (%)	80			
n per sequence group	36			

图 1-42 nQuery Advisor 7.0 关于例 1-17 样本量估计的参数设置与计算结果

SAS 9.2 软件实现:

proc IML;

start MTE1co ( a, sd1, sd2, p, Leld, Ueld, ed, power);

error = 0;

if ( a > 1 | a < 0 ) then do; error = 1; print "error"  
"Test significance level must be in 0-1"; end;

if ( p > 1 | p < 0 ) then do; error = 1; print "error"  
"The correlation coefficient of group 1 and group 2 must be in 0-1"; end;

if ( sd1 < 0 ) then do; error = 1; print "error"  
"Standard deviation of group 1 must be > = 0"; end;

if ( sd2 < 0 ) then do; error = 1; print "error"  
"Standard deviation of group 2 must be > = 0"; end;

if ( Leld > Ueld ) then do; error = 1; print "error"  
"Lower equivalence limit difference must be < = Upper equivalence limit difference"; end;

if ( Ueld < Leld ) then do; error = 1; print "error"  
"Upper equivalence limit difference must be > = Lower equivalence limit difference"; end;

if ( ed < = Leld | ed > = Ueld ) then do; error = 1;  
print "error" "Expected difference must be in Leld-Ueld"; end;

if ( power > 100 | power < 1 ) then do; error = 1;  
print "error" "Power (%) must be in 1-100"; end;

if ( error = 1 ) then stop;  
if ( error = 0 ) then do;

SDD = sqrt( sd1##2 + sd2##2 - 2#p#sd1#sd2 );  
MSE = ( SDD/sqrt( 2 ) )##2; ca = sqrt( MSE );  
sd = sqrt( MSE )/sqrt( 2 ); n = 2;

do until( pw1 + pw2 - 1 > = power/100 );  
L\_ncp = abs( ed - Leld )#sqrt( n )/( sd#sqrt( 2 ) );  
U\_ncp = abs( ed - Ueld )#sqrt( n )/( sd#sqrt( 2 ) );  
df = 2 \* ( n - 1 ); t = tinv( 1 - a, df );  
pw1 = 1 - probt( t, df, L\_ncp );  
pw2 = 1 - probt( t, df, U\_ncp );  
n = n + 0.01; end;

n = ceil( n - 0.01 );

```

print a[ label = "Test significance level" ]
Leld [ label = "Lower equivalence limit differ-
ence" ]
Ueld [ label = "Upper equivalence limit differ-
ence" ]
ed [ label = "Expected difference" ]
ca [ label = "Crossover ANOVA sqrt(MSE)" ]

```

```

power[ label = "Power( % )" ]
n[ label = "n per sequence group" ];end;
finish MTElco;
run MTElco(0.025,0.2,0.2,0.6,-0.07,0.07,0,80);
quit;
SAS 运行结果:

```

Test significance level	Lower equivalence limit difference	Upper equivalence limit difference	Expected difference	Crossover ANOVA sqrt(MSE)	Power (%)	n per sequence group
0.025	-0.07	0.07	0	0.1264911	80	36

图 1-43 nQuery Advisor 7.0 关于例 1-17 样本量估计的参数设置与计算结果

1.2.2.4 基于比值两组设计的等效性检验(连续变量)

方法: Schuirmann (1987) 等<sup>[12-14]</sup> 提出的基于比值两组设计的等效性检验效能及样本量估计是建立在非中心参数为  $\tau_1$  和  $\tau_2$  的非中心  $t$  分布上,其检验效能的计算公式为:

$$1 - \beta = 1 - \text{Probt}(t_{1-\alpha, 2(n-1)}, 2(n-1), \tau_2) - \text{Probt}(t_{1-\alpha, 2(n-1)}, 2(n-1), \tau_1) \quad (1-21)$$

式中,  $\tau_1$  和  $\tau_2$  为非中心参数

$$\tau_1 = \frac{\left| \ln\left(\frac{\mu_T}{\mu_S}\right) - \ln(\Delta_L) \right| \sqrt{n}}{\sqrt{2\sigma^2}};$$

$$\tau_2 = \frac{\left| \ln\left(\frac{\mu_T}{\mu_S}\right) - \ln(\Delta_U) \right| \sqrt{n}}{\sqrt{2\sigma^2}} \quad (1-22)$$

$\Delta_L$  为下界,  $\Delta_U$  为上界,  $\sigma = \sqrt{\ln(1 + CV^2)}$ ,  $CV$  为变异系数。

在计算样本量时,一般先设定样本量初始值,然后迭代样本量直到所得的检验效能满足条件为止。此时的样本量,即研究所需的样本量。

【例 1-18】某临床试验欲验证一种降血压的仿制药等效于其原研药。由预试验数据获知,给药 48 小时的血药浓度的曲线下面积的均数和标准差分别为 230 和 45,数据服从对数正态分布。根据临床专家的观点,仿制药与其原研药的均数比值不低于 0.80 且不高于 1.25 可认为临床等效。若采用平衡设计,试估计检验效能为 90% 时的样本量。

nQuery Advisor 7.0 实现:

设定检验水准  $\alpha = 0.05$ , 检验效能取  $1 - \beta = 90\%$ 。依据上述基础数据可知,  $\Delta_L = 0.8$ ,  $\Delta_U = 1.25$ ,  $CV = 45/230 = 0.196$ , 假设总体均数比值为 1。

在 nQuery Advisor 7.0 主菜单选择:

- Goal: Make Conclusion Using:  Means
- Number of Groups:  Two
- Analysis Method:  Equivalence

方法框中选择:  
TOST for equivalence for ratio of means (logscale) for two-group design。

在弹出的样本量计算窗口将各参数键入,如图 1-44 所示,结果为  $n = 21$ 。

SAS 9.2 软件实现:  
PROC IML;

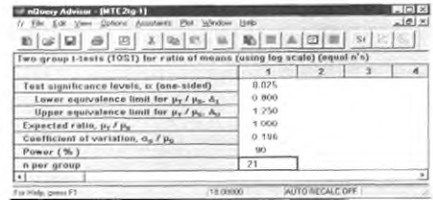


图 1-44 nQuery Advisor 7.0 关于例 1-18 样本量估计的参数设置与计算结果

```

start MTE2tg(a, Lelr, Uelr, rm, CV, power);
error = 0;
if(a > 1 | a < 0) then do; error = 1; print "error"
"Test significance level must be in 0-1"; end;
if(CV < 0) then do; error = 1; print "error" "CV
must be > = 0"; end;
if(Lelr > Uelr) then do; error = 1; print "error"
"Lower equivalence limit ratio must be < = Upper e-
quivalence limit ratio"; end;
if(Uelr < Lelr) then do; error = 1; print "error"
"Upper equivalence limit ratio must be > = Lower e-
quivalence limit ratio"; end;
if(rm < = Lelr | rm > = Uelr) then do; error = 1;
print "error" "Expected ratio must be in Leld-Ueld";
end;
if(rm < = 0) then do; error = 1; print "error" "Ex-
pected ratio must be > 0"; end;
if(power > 100 | power < 1) then do; error = 1;
print "error" "Power( % ) must be in 1-100"; end;

```

(下转第 459 页)

```

"Upper equivalence limit ratio must be > = Lower e-
quivalence limit ratio"; end;
    if (rm <= Lelr | rm >= Uelr) then do; error = 1;
print "error" "Expected ratio must be in Lelr-Uelr";
end;
    if (rm <= 0) then do; error = 1; print "error" "Ex-
pected ratio must be >0"; end;
    if (power > 100 | power < 1) then do; error = 1;
print "error" "Power(%) must be in 1-100"; end;
    if (error = 1) then stop;
    if (error = 0) then do; n = 2;
do until (pw1 + pw2 - 1 >= power / 100);
    L_ncp = abs (rm - Lelr) # sqrt (2 # n) / sqrt ( CVb ## 2 #
(1 - Lelr) ## 2 + CVi ## 2 * (1 + Lelr ## 2) );
    U_ncp = abs (rm - Uelr) # sqrt (2 # n) / sqrt ( CVb ## 2 #
(1 - Uelr) ## 2 + CVi ## 2 * (1 + Uelr ## 2) );

```

```

df = 2 * (n - 1); t = tinv (1 - a, df);
pw1 = 1 - probt (t, df, L_ncp);
pw2 = 1 - probt (t, df, U_ncp);
n = n + 0.01; end; n = ceil (n - 0.01);
print a [ label = "Test significance level" ]
Lelr [ label = "Lower equivalence limit ratio" ]
Uelr [ label = "Upper equivalence limit ratio" ]
rm [ label = "Expected ratio" ]
CVb [ label = "CV between subjects" ]
CVi [ label = "CV intrasubject" ]
power [ label = "Power(%) " ]
n [ label = "n per group" ]; end;
finish MTE4;
run MTE4 (0.025, 0.9, 1.111, 1, 0.206, 0.158,
90); quit;
SAS 运行结果:

```

Test significance level	Lower equivalence limit ratio	Upper equivalence limit ratio	Expected ratio	CV between subjects	CV intrasubject	Power (%)	n per group
0.025	0.9	1.111	1	0.206	0.158	90	31

图 1-51 SAS 9.2 关于例 1-21 样本量估计的参数设置与计算结果

(上接第 455 页)

```

if (error = 1) then stop;
if (error = 0) then do;
sd = sqrt (log (1 + CV ## 2) ); n = 2;
do until (pw1 + pw2 - 1 >= power / 100);
    L_ncp = abs (log (rm) - log (Lelr) ) # sqrt (n) / (sd #
sqrt (2) );
    U_ncp = abs (log (rm) - log (Uelr) ) # sqrt (n) / (sd #
sqrt (2) );
df = 2 * (n - 1); t = tinv (1 - a, df);
pw1 = 1 - probt (t, df, L_ncp);
pw2 = 1 - probt (t, df, U_ncp);
n = n + 0.01; end;

```

```

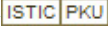
n = ceil (n - 0.01);
print a [ label = "Test significance level" ]
Lelr [ label = "Lower equivalence limit ratio" ]
Uelr [ label = "Upper equivalence limit ratio" ]
rm [ label = "Expected ratio" ]
CV [ label = "Coefficient of variation" ]
power [ label = "Power(%) " ]
n [ label = "n per group" ]; end;
finish MTE2tg;
run MTE2tg (0.025, 0.8, 1.25, 1, 0.196, 90);
quit;
SAS 运行结果:

```

Test significance level	Lower equivalence limit ratio	Upper equivalence limit ratio	Expected ratio	Coefficient of variation	Power (%)	n per group
0.025	0.8	1.25	1	0.196	90	21

图 1-45 SAS 9.2 关于例 1-18 样本量估计的参数设置与计算结果

# 样本量估计及其在nQuery和SAS软件上的实现——均数比较 (五)

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