A Phase II, Placebo-Controlled, Double-Blind Study Of The Selegiline Transdermal System (STS) In The Treatment Of HIV-Associated Cognitive Impairment

Three treatment arms:
- 0.5 mg x20 cm² patch
- 1.0 mg x20 cm² patch
- 2.0 placebo patch

Primary Endpoint: Change in neuropsychological function as measured by a composite \( z \)-score on a battery of tests (including auditory verbal learning, grooved pegboard, and CalCAP). (a continuous outcome)

Compare: 0.5 mg x20 cm² patch vs placebo and 1.0 mg x20 cm² patch vs placebo

Envision doing a t-test for each comparison. Since we would like the overall (experiment wise) Type I error rate to be 0.05, then we perform individual each test at 0.025.

Two-sample
Two-sided
Desire 80% power
Assume that you wish to detect a 0.75SD difference between the arms.
Equal allocation between arms.

.sampsi 0 .75, sd(1) p(.8) a(.025)

\[ n_1 = n_2 = 34 \]

Thus \( n_3 = 34 \).

Assume 10% drop out rate:
\[ N_{adj} = 102/(1-0.1) = 113.333 \]

Assume 10% noncompliance rate:
\[ N_{adj2} = 113.33/((1-0.1)^2) = 139.92 \]

Assume that we cannot do t-test (data is not normal) and must do nonparametric test:
\[ N_{adj3} = 139.92/(0.864) = 161.94 \]

Thus need 54 subjects per group.