Q14 Describe the factors that determine the sample size of a randomised clinical trial (60% of marks). Describe the differences between a parametric and a non-parametric statistical test and give one example of a parametric test and one example of a non-parametric test (March 2009)

RCT

- 'Gold standard' level I and II evidence as per NHMRC classification
- Prospective study
- Eligible subjects are randomised to different treatment groups and the differences in outcome variables are then compared

FACTORS DETERMINING SAMPLE SIZE

- **Type I error (alpha)** - The probability of falsely rejecting the null hypothesis (H_0) and detecting a statistically significant difference when in reality no statistically significant difference exists, ie; the chance of a false-positive result. A lower value of alpha requires a larger sample size. Normal alpha value 0.05
- **Type II error (beta)** - The probability of falsely accepting H_0 and not detecting a statistically significant difference when a specified difference between the groups truly exists, ie; the chance of a false-negative result. A lower value of beta requires a larger sample size. Normal beta value 0.05-0.2
- **Power** - The probability of correctly rejecting H_0 and detecting a statistically significant difference when a specified difference between the groups in reality exists. Power is equal to (1-beta).
- **Effect size** - the minimal difference between the studied groups that the investigator considers biologically plausible and clinically relevant. The smaller the effect size, the larger the sample size needed
- **Variability** - the greater the variability in the outcome variable, the larger the sample size required to assess whether an observed effect is a true effect

PARAMETRIC TEST

Parametric statistical procedures are based on estimates or assumptions of the shape of the distribution in the underlying population (ie, they assume a normal distribution). They are based on the actual magnitude of values and can only be used for data on a numerical scale. Examples include the paired t test and ANOVA.

NON PARAMETRIC TEST

Nonparametric statistical procedures make no assumptions about the shape or parameters of the population distribution for a given variable. They do not rely on estimation of parameters such as mean or standard deviation. Examples include the Wilcoxon rank-sum test and Spearman's rank correlation.