Appraisal and synthesis of the study

Health & Medicine

2. If the study was well or poorly designed

The study design was very thorough using the prospective, randomized, open, blinded endpoint evaluation (PROBE) design. The sample size provides an adequate statistical power of 80%. Statistical analysis used Kaplan-Meier survival curves will take censored data into account, namely if a patient withdraws from the study and the variance of patient simvastatin doses. Log-rank analysis and the Cox's regression model are appropriate testing methods widely used in survival analysis to establish the efficacy of a new treatment (aspirin and statins) compared to a control treatment (statins) in time to event measurements. Use of the Mantel-Haenszel procedure to test subgroups will be effective providing subgroup sample sizes are large enough to obtain stable estimates. Interim analysis after 50% of events had occurred leaves scope for adjustments to the study.

3. If the study setting was relevant

The study setting was relevant because the sample consisted of patients who had no history of cardiovascular disease, who were type 1 and type 2 diabetic and who were already prescribed or candidates for the use of statins.

4. If the participants were appropriately defined, selected representatively, followed up without significant loss, etc

Participants were appropriately defined for the study and selected based on appropriate criteria. A clear follow-up plan is defined to maintain patient health with changes to simvastatin control treatment doses allowed based on clinical judgment If LDL cholesterol levels were ≥100 mg/dL (2. 59 mmol/L). Losses are expected <= normal cardiovascular event percentages.

5. If the intervention was appropriate (clearly described, practical)

Continued follow up during the trials allows for appropriate intervention to take place but intervention methods are not clearly defined.

6. If the endpoint(s) were relevant to the health of patients or populations, well defined and measured

The relevant conditions of the patients were all detailed in the study of population inclusion and exclusion criteria. The endpoints are relevant to the health of the patients and the statistical analysis shall clearly define and measure the outcomes.

7. If the study findings were important from public health or clinical perspective

The study findings will be important from a public health perspective because they assess the putative additive effects of established preventative cardiovascular event drugs (aspirin and statins) to prevent cardiovascular events from occurring in a society with ever-increasing levels of diabetes.

8. If the study had sufficient power (was large enough and long enough to detect worthwhile effects)

The study is large enough to meet the research criteria because it is designed to be flexible in size and time-span in order to retrieve the desired data for analysis.