AIM HIGH

AIM HIGH: Niacin Plus Statin to Prevent Vascular Events

Study Phase III

Purpose

The purpose of this study is to determine whether raising "good cholesterol" with a drug based on the vitamin niacin, while lowering "bad cholesterol" with a statin drug, can prevent more heart disease than the statin alone.

The study population will include those who meet the following inclusion/exclusion criteria, some of which are:

Inclusion Criteria

- Demographics: ≥ 45 years of age.
- Signed & dated, written informed consent to participate in this study.
- Subjects with established vascular disease and atherogenic dyslipidemia
- Established vascular disease defined as one or more of the following:
  1) Documented coronary artery disease (CAD)
  2) Documented cerebrovascular or carotid disease
  3) Documented symptomatic peripheral arterial disease (PAD)

- Atherogenic dyslipidemia defined as:
  1) LDL-C ≤160 mg/dL (4.1 mmol/L)
  2) HDL-C ≤ 40 mg/dL (1.0 mmol/L) for men or
  3) HDL-C ≤ 50 mg/dL (1.3 mmol/L) for women
  4) TG ≥ 150 mg/dL (1.7 mmol/L) and ≤ 400 mg/dL (4.5 mmol/L)

- For subjects entering the trial on a statin:
  1) the upper limit of LDL-C is adjusted according to the specific statin and statin dose
  2) HDL-C ≤ 42 mg/dL(1.1mmol/L) for men or
  3) HDL-C ≤ 53 mg/dL (1.4mmol/L) for women
  4) TG ≥ 125 mg/dL (1.4 mmol/L) and ≤ 400 mg/dL (4.5mmol/L)

Exclusion Criteria

- Coronary artery bypass graft (CABG) surgery within 5 years of planned enrollment (run-in phase)
- Percutaneous coronary intervention (PCI) within 4 weeks of planned enrollment (run-in phase)
- Hospitalization for acute coronary syndrome and discharge within 4 weeks of planned enrollment (run-in phase)
- Fasting glucose > 180 mg/dL (10 mmol/L) or hemoglobin A1C > 9%
- For subjects with diabetes, inability or refusal to use a glucometer for home monitoring of blood glucose

To inquire if you are eligible for this study or hear more about it, please contact:

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