

# The Physicians' Health Study II

## Multivitamins in the Prevention of Cardiovascular Disease in Men

**Background:** Multivitamins (MVM) are used in order to prevent vitamin and mineral deficiency by more than half of all adult Americans. MVM in the prevention of chronic diseases is an area for further study. **Objective:** Test the effects of supplementation use on the risk of CVD and mortality; determine if supplements decrease the risk of major CV events in men.

**Methods:** 14,641 U.S. male physicians aged  $\geq 50$  years, including 754 (5.1%) with prevalent CVD, were randomized in a double-blind, placebo controlled RCT, and assigned to active (Centrum Silver) or placebo MVM. Pts. followed for an average 11.2 years. Primary analysis based on intention to treat.

**Primary Endpoints:** Major CV events (including nonfatal MI, nonfatal stroke and CVD death.) **Secondary Endpoints:** Total MI and total stroke **Other endpoints:** Fatal and nonfatal MI and stroke, CVD, ischemic and hemorrhagic stroke and total MI

**Results:** 1732 major CVD events at follow-up of 11.2 yrs. (10.7 to 13.3). No sig effect of MVM on CVD events vs. placebo. 11 and 10.8 events per 1000 person years. Daily MVM was not associated with total mortality (HR, .94; 95% ci, .88-1.02; p=.13). No effect on total MI (3.9 and 4.2 events per 1000 person years; HR, 1.06; 95% CI, .91-1.23; p=.39). CV event did not differ in daily MVM use for those with or without history of CVD at baseline (p=.62 for interaction).

**Conclusions:** No effects seen using intervention. Additional study needed. An individual's nutritional status should serve as a basis for taking MVM to prevent vitamin and mineral deficiency.

