

Bempedoic acid and cardiovascular outcomes in statin-intolerant patients: CLEAR Outcomes

Nissen SE, et al. N Engl J Med. 2023;388:1353–1364

Background

CLEAR Outcomes is the cardiovascular outcomes trial for the ATP citrate lyase inhibitor bempedoic acid

It is already approved for **reducing LDL cholesterol** in patients intolerant to statins

Patients and methods

Double-blind, randomised, placebo-controlled trial

Adults with **LDL cholesterol ≥ 100 mg/dL** and **high cardiovascular risk***

Provided written confirmation of **statin intolerance**



4-week placebo run-in

N=13,970 with $\geq 80\%$ adherence randomised

n=6,978 to placebo

n=6,992 to bempedoic acid 180 mg/day

Results: 4-point major adverse cardiac events[†]

Placebo
13.3%

Bempedoic acid
180 mg/day
11.7%

HR=0.87; 95% CI, 0.79–0.96; P=0.004

Safety



Treatment-emergent adverse events **occurred at similar rates** in the two groups



Myalgias and **rhabdomyolysis** were infrequent in both groups



Cholelithiasis was more common in the **bempedoic acid** than **placebo** groups, which was not seen in previous trials

Takeaway

Lipid lowering using bempedoic acid results in a **significantly reduced risk** of **major adverse cardiovascular events**

Abbreviations: ATP, adenosine triphosphate; CI, confidence interval; HR, hazard ratio; LDL, low-density lipoprotein.

*High risk defined as established coronary artery disease, peripheral arterial disease or cerebrovascular disease; or as Reynolds risk score $>30\%$ or SCORE $>7.5\%$ over 10 years, coronary artery calcium score >400 Agatston units, or diabetes in women >65 years or men >60 years.

[†]Nonfatal myocardial infarction, nonfatal stroke, cardiovascular mortality, coronary revascularisation; median follow-up = 40.6 months.

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