

# Bempedoic Acid and Cardiovascular Outcomes in Statin-Intolerant Patients: *The CLEAR Outcomes Trial*

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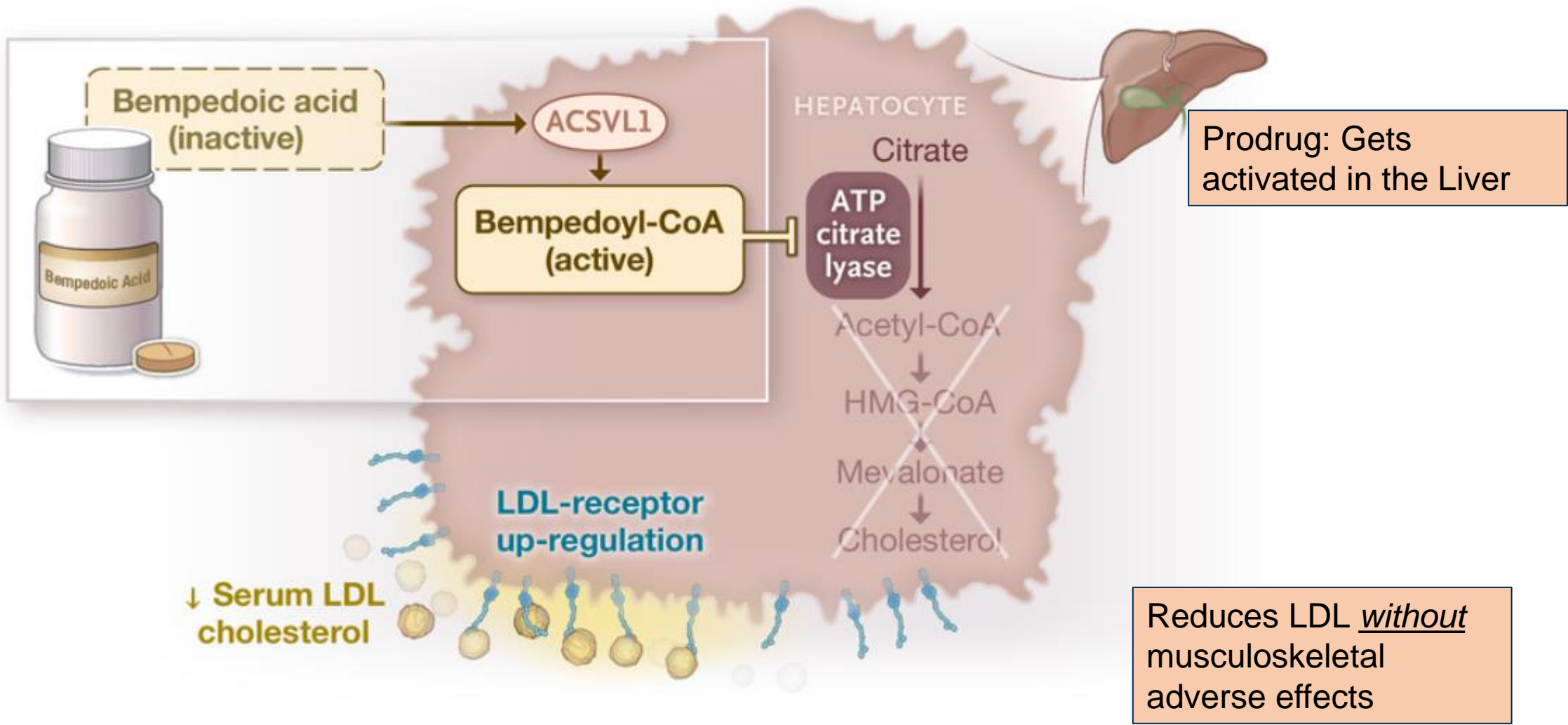


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# CLEAR (Cholesterol Lowering via Bempedoic Acid an ACL-Inhibiting Regimen) Outcomes trial

# Clinical Trial

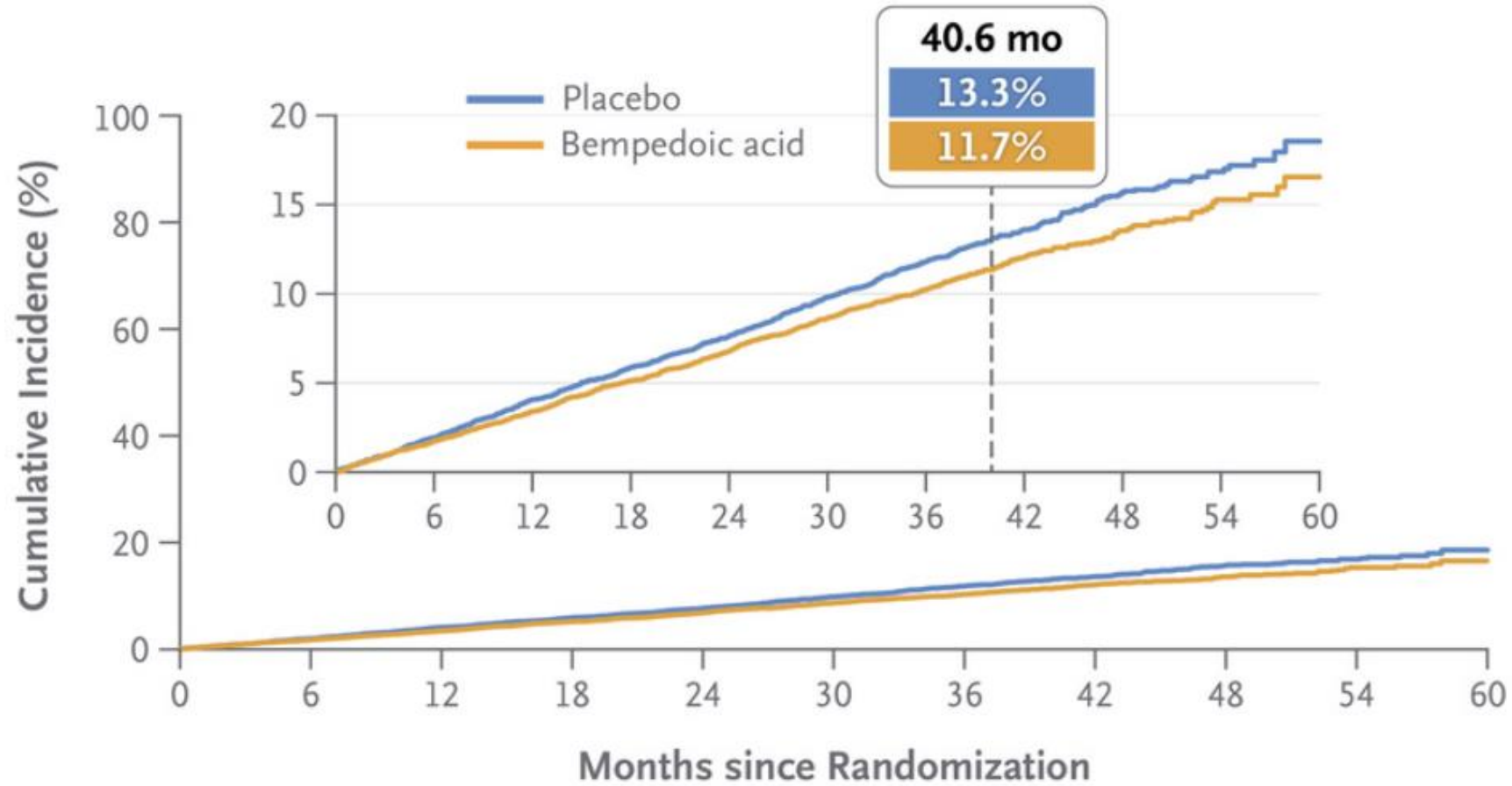
- Design: International Double-Blind Randomized, Placebo-Controlled
- Population: 13,970 patients 18-85 years old with increased CV risk\* who were unable or unwilling to take statin therapy
- Intervention: 180mg of Bempedoic Acid or Placebo Daily

# Primary End Point: Four Component Composite of Major Adverse Cardiovascular Events (MACE)

- Death from Cardiovascular Causes
- Nonfatal Myocardial Infarction
- Non-Fatal Stroke
- Coronary Revascularization

## Four-Component Composite of Major Adverse Cardiovascular Events

HR, 0.87 (95% CI, 0.79–0.96); P=0.004



# Composite Components

Outcome	Bempedoic Acid (N=6992)	Placebo (N=6978)	Hazard Ratio (95% CI)
<i>number of patients (%)</i>			
Non-fatal MI	236 (3.4)	317 (4.5)	0.73 (0.62-0.87)
Fatal MI	29 (0.4)	21 (0.3)	1.38 (0.79-2.42)
Non-fatal stroke	119 (1.7)	144 (2.1)	0.82 (0.64-1.05)
Fatal stroke	18 (0.3)	16 (0.2)	1.12 (0.57-2.20)
Fatal and nonfatal non-hemorrhagic stroke	118 (1.7)	150 (2.1)	0.78 (0.61-0.99)
Fatal and nonfatal hemorrhagic stroke	20 (0.3)	9 (0.1)	2.21 (1.01-4.85)

# Safety

Adverse Events		
	Bempedoic acid (N=7001)	Placebo (N=6964)
	<i>no. of patients (%)</i>	
Any adverse event	6040 (86.3)	5919 (85.0)
Elevated hepatic enzymes	317 (4.5)	209 (3.0)
Renal impairment	802 (11.5)	599 (8.6)
Hyperuricemia	763 (10.9)	393 (5.6)
Gout	215 (3.1)	143 (2.1)
Cholelithiasis	152 (2.2)	81 (1.2)

<b>Skeletal Muscle Events Leading to Drug Discontinuation</b>		
Muscle Disorder Adverse Event	202 (2.9)	221 (3.2)
Myalgia	124 (1.8)	129 (1.9)
Pain in the extremity	35 (0.5)	31 (0.4)
Muscle spasms	31 (0.4)	49 (0.7)
Muscular weakness	8 (0.1)	11 (0.2)
Blood creatine phosphokinase increased	5 (0.1)	5 (0.1)
Myopathy	2 (<0.1)	2 (<0.1)
Musculoskeletal discomfort	1 (<0.1)	0
Myositis	0	1 (<0.1)

# Industry Involvement



**C5 Research**

Cleveland Clinic Coordinating Center for Clinical Research

# Conclusions

- Bempedoic Acid Reduces Major Cardiovascular Events Compared to Placebo in **Statin-Intolerant Patients**
  - More specifically Non-Fatal Events
- No clear effect on mortality benefit compared to placebo
- Similar muscle pain side effect profile compared to placebo
- Could benefit from further investigations

Thank you!