PROVE IT - TIMI 22

Protocol Design

Patients stabilized post ACS <10d
Total cholesterol <240 mg/dL (N=4000)

ASA & standard medical therapy

2x2 factorial design

Follow-up visit day 15

Follow-up visit day 30 then q4 months (average 2 years, minimum 18 months)

1° Endpoint: death, MI, stroke, rehosp for UA, revasc*

* Revascularization includes only procedures occurring > 30d post randomization

Cannon CP, Am Heart J 2002; 89:860-61
Note: Changes in LDL-C may differ from prior trials:
- 25% of patients on statins prior to ACS event
- ACS response lowers LDL-C from true baseline

Lipid Results

DEATH, NON-FATAL MI, OR URGENT REVASCULARIZATION

Percent patients with events

- Pravastatin 40 mg: 16.7%
- Atorvastatin 80 mg: 12.9%

RRR 25%
P = 0.0004

DEATH, NON-FATAL MI, OR URGENT REVASCULARIZATION AT 30 DAYS

Hazard Ratio = 0.67
p = 0.04

Pravastatin 40 mg
Atorvastatin 80 mg

Median C-reactive protein (hsCRP) levels by treatment

Pravastatin 40mg (n=1873)

Atorvastatin 80mg (n=1872)

Ridker PM, J Am Coll Cardiol 2005; 45:1644-48
Lipid Results

Risk of Death or MI after Day 30

- pravastatin 40mg
- atorvastatin 80mg

Quintiles of hsCRP at day 30

P=0.005 for prava
P=0.6 for atorva

Ridker PM, J Am Coll Cardiol 2005; 45:1644-48
Death from Any Cause or a Major CV Event

Placebo (25.1%)

Gatifloxacin (23.7%)

5% RR
(P = 0.41)