

Aspirin 81mg *vs.* 325mg UCLA Recruitment Plan







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2014 AHA/ACC NSTE-ACS Guidelines



[For patients who experience NSTE-ACS], a maintenance dose of aspirin (81 mg/d to 325 mg/d) should be continued indefinitely.





(Circulation. 2014;130:2354-2394.)

Main objectives

To perform a large, pragmatic clinical trial

Cto compare the effectiveness and safety of two doses of aspirin (81 mg and 325 mg)

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 Primary effectiveness endpoint: Composite of all-cause mortality, hospitalization for MI, or hospitalization for stroke

Primary safety endpoint: Hospitalization for major bleeding

Pragmatic research: e-data collection



Computable Phenotype

INCLUSION

Known CAD

- History of MI
- Prior coronary revascularization
- C≥18 years of age
- Estimated 3-year MACE risk >8%
 - Age >65 years
 - Creatinine >1.5 mg/dL
 - Diabetes mellitus (type 1 or 2)
 - Known 3-vessel CAD
 - Known Cerebrovascular disease or PAD
 - Current smoker

EXCLUSION

- C Allergy or intolerance to ≤325 mg aspirin per day
- Current use of warfarin, NOAC, or Ticagrelor
- Pregnant or nursing an infant
- Significant GI bleed within past 12 months
- Significant bleeding disorder

"Pragmatic" Study Design



pSCANNER Recruitment Approach

Enrollment goals

- UCLA: 1,340 patients
- UCI: 660 patients

Eligible participants will be contacted via:

- 1. Mail and patient portal message (if portal user)
- 2. Phone calls
- 3. Face-to-face contact in clinic by study RA
- Each contact will provide a golden ticket number that the patient can use to enter the study web portal

C PCP, cardiologist will be pre-notified of eligible patients

- Opportunity opt patients out who should not participate
- Study fliers provided for clinicians to hand out during visits
- FAQ for physicians to help them answer patient questions

ADAPTABLE timeline

CUCLA

- 12,059 patients match computable phenotype
 - 6,079 had an ambulatory visit with their PCP or cardiologist in the last 3 years
- Plan to launch recruitment this month, continue waves through Summer, 2017

CUC Irvine

- Finalizing subcontract and IRB
- Asked by Duke to hold until UCLA well underway

pSCANNER Study Team

CUCLA

- PI: Douglas S. Bell, MD, PhD
- Co-I: Gregg Fonarow, MD (Cardiology)
- Project Manager: Marianne Zachariah

CUC Irvine

- PI: Shaista Malik, MD (Cardiology)
- Project Manager: Roni Bracha

Reference slides