Adaptable

The Aspirin Study

Aspirin 81mg vs. 325mg

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

To perform a large, pragmatic clinical trial
- to compare the effectiveness and safety of two doses of aspirin (81 mg and 325 mg)
- in high-risk patients with coronary artery disease

- **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

N=20,000

ADAPTABLE enrollee

Baseline data

Web portal follow-up
- Randomized to 3 vs 6 mos contact
- Patient-reported hospitalizations
- Medication use
- Health outcomes

PCORnet Coordinating Center follow-up
- Via Common Data Model
- Validated coding algorithms for endpoints

CMS and private health plans follow-up
- Longitudinal health outcomes
- Validated coding algorithms for endpoints

DCRI call center
- Patients who miss 2 contacts
- Patient-reported hospitalizations
- Medication use
- Health outcomes

Death ascertainment
National Death Index (NDI) & Social Security Database
INCLUSION

- Known CAD
  - History of MI
  - Prior coronary revascularization
- ≥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

- 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

Patients matching the computable phenotype identified through EHR search

Patients contacted (via mail, email, phone, face-to-face) with link to study website

Study web portal conducts informed consent and random assignment of aspirin dose

ASA 81 mg QD

ASA 325 mg QD

Follow-up through study website: Every 3–6 months Supplemented with CDM/claims data

Duration: Enrollment over 24 months; maximum follow-up of 30 months
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

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
UCLA

- 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

UC Irvine

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

**UCLA**
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Reference slides