ClinicalTrials.gov
Protocol Registration System

Protocol Registration Receipt
11/13/2012

Association Between Low Dose Acetylsalicylic Acid (ASA) and Proton Pump Inhibitors and Risk of Acute Myocardial Infarction or Coronary Heart Disease Death

This study has been completed.

Sponsor:	AstraZeneca
Collaborators:	
Information provided by (Responsible Party):	AstraZeneca
ClinicalTrials.gov Identifier:	NCT01360073

Purpose

The purpose of this study is to estimate the risk of myocardial infarction (MI)/coronary death associated with use of monotherapy low dose ASA (single antiplatelet) as well as concomitant use of monotherapy low dose ASA and proton pump inhibitors (PPIs) in patients with serious coronary heart disease using two UK primary care databases.

Condition
Nonfatal Myocardial Infarction Coronary Death

Study Type: Observational
Study Design: Cohort, Retrospective
Official Title: Association Between Low Dose Acetylsalicylic Acid (ASA) and Proton Pump Inhibitors and Risk of Acute Myocardial Infarction or Coronary Heart Disease Death - Nested Case Control Analyses in a Cohort of Patients With Acute Serious Coronary Heart Disease

Further study details as provided by AstraZeneca:

Biospecimen Retention: None Retained
Primary Outcome Measure:

- Nonfatal MI or coronary death [Time Frame: Up to eight years from entry into study cohort] [Designated as safety issue: Yes]

Enrollment: 42542
Study Start Date: July 2011
Study Completion Date: December 2011
Primary Completion Date: December 2011

Groups/Cohorts	Interventions
Cases Cases with nonfatal MI or coronary death	
Controls Age, sex, and calendar-year matched controls sampled from the original study cohort to be a round number of at least four times the number of cases	

Number of Anticipated Subjects: In case-control analysis: 10.000-15.000 participants

Eligibility

Individuals aged 50–84 years who from 1 January 2000 to 31 December 2007 had a documented evidence of a hospitalization for a serious acute coronary event (MI, revascularization of coronary arteries or unstable angina) and who were alive 1 month after this event in two primary care clinical practice databases in the UK: General Practice Research Database (GPRD) and The Health Improvement Network (THIN).

Sampling Method: Non-Probability Sample
Ages Eligible for Study: 50 Years to 84 Years
Genders Eligible for Study: Both

Inclusion Criteria:

- As above (study population description).
- All individuals aged 50-84 years with at least one year of enrolment with the primary care physician (PCP) and a computerized prescription history of at least one year before the start of the study.

Exclusion Criteria:

- Recorded diagnosis of cancer prior to study start.
- Patients aged ≥ 70 years with a follow-up longer than one year if having fewer than two recorded consultations with a primary care physician (PCP) during their entire follow-up (proxy for incomplete and invalid data recording

Contacts and Locations

Locations

Spain

Research Site

Madrid, Spain

Sweden

Research Site

Molndal, Sweden

Investigators

Principal Investigator:	Luis A Garcia Rodriguez	CEIFE (Centro Español de Investigación Farmacoepidemiológica)

More Information

Responsible Party:	AstraZeneca
Study ID Numbers:	D961FN00007
Health Authority:	Europe: BfArM (Bundesinstitut fur Arznemittel und Medizineprodukte)