**Title of Trial:** The Efficacy of Influenza Vaccination in Patients With Coronary Artery Diseases

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):** NCT 00607217

**Sponsors:** Shahid Beheshti Medical University

**Study Design:** The phase 2-3, Interventional, Randomized, Efficacy Study, Single Blind

This study aims to identify the efficacy of influenza vaccination in including coronary artery disease (CAD) individuals in terms of both serologic response (as compared with healthy individuals) and clinical outcomes (as compared with CAD patients not vaccinated)

**Vaccine:** TIV

  **Manufacturer:** Solvay Pharmaceuticals, The Netherlands

  **Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):** Inactivated split virus

  **Adjuvant:** None

  **Delivery system/site:** One intramuscular injection

**Doses (antigen and adjuvant):** 15 µg each strain

**Study population:** 137 patients with coronary artery disease

  **Age range:** ≥25y

**Inclusion Criteria:**

- Coronary artery disease (CAD) group (CAD-Exp and CAD-Control):
  - Patients with the diagnosis of acute, evolving or recent MI (after recovered the acute phase) as defined by: 1. Typical rise and gradual fall (troponin) or more rapid rise and fall (CK-MB) of biochemical markers of myocardial necrosis with at least one of the following:
    - Ischemic symptoms
    - Development of pathologic Qwaves on the ECG
    - ECG changes indicative of ischemia (ST segment elevation or depression); OR
    - Coronary artery intervention (e.g., coronary angioplasty). 2. Pathologic findings of an acute MI

- Patients with stable angina pectoris (SA) and documented coronary artery stenosis (angiography).

- Healthy Control group: healthy controls, proportionally matched by gender and age with the patient group (separate control groups for MI and SA patients).

**Exclusion Criteria:**

- Any acute disease
- Chronic liver or kidney diseases
- Conditions accompanied by immunosuppression (like organ transplantation, HIV)
- Diagnosed malignancy
- Incubation with influenza vaccine within the past 5 years
- Any psychological disease that interferes with regular follow-up
- Congestive heart failure (Killip class IV)
- Unstable angina; AND
Clinical Endpoints Assessed:

Primary Outcome Measures:
• Influenza infection [Time Frame: 6 months]
• Serologic response (≥4-fold HI titer rise) to each of the 3 antigens of the trivalent vaccine of the 2006-07 campaign [Solomon Islands/3/2006(H1N1), Wisconsin/67/2005 (H3N2), and Malaysia/2506/2004 - like strains] [Time Frame: 1 month]

Secondary Outcome Measures:
• Magnitude of change in the antibody titer against each of the three influenza vaccine antigens [Time Frame: 1 month]
• Protective antibody (≥1:40) titer after vaccination [Time Frame: 1 month]
• Influenza-related death [Time Frame: 6 months]

Results:

Safety:

Immunogenicity

GMTs:

GMT Ratios (post:pre):

Per cent responding (4 fold or greater rise and definition for reporting):
≥4 fold increase in HI after I dose:
66% H1N1
73% H3N2
56% B

Per cent responders at specified tite:
HI≥40 after I dose:
96% H1N1
99% H3N2
98% B

Others assays:

Status of trial (ongoing/completed): 2007-2008