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Main

Note: This record shows only 21 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, or for additional information about this trial, click on the URL below to go to the source record in the primary register.

Register: CTRI
Last refreshed on: 11 September 2018
Main ID: CTRI/2017/10/010030
Date of registration: 06-10-2017
Prospective Registration: No
Primary sponsor: Dr Lokeswara Rao Sajja
Public title: Comparison of graft patency in on-pump heart surgery versus off-pump heart Surgery
Scientific title: Prospective Randomized comparison of Off-pump and On-pump Multi-vessel Coronary artery bypass surgery To Evaluate outcomes and graft patency
Date of first enrolment: 23-03-2016
Target sample size: 400
Recruitment status: Completed
URL: <http://www.ctri.nic.in/Clinicaltrials/pmaindet2.php?trialid=14112>
Study type: Interventional
Study design: Randomized, Crossover Trial Method of generating randomization sequence:Stratified block randomization Method of allocation concealment:Sequentially numbered, sealed, opaque envelopes Blinding and masking:Open Label
Phase: N/A

Countries of recruitment

India

Contacts

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Key inclusion & exclusion criteria

Inclusion criteria: 1. Male or female aged ≥21years to ≤70years

2. Able to provide written informed consent

3. Patients with significant CAD with significant triple vessel disease or LMCA stenosis angiographically documented ischemia due to multi vessel coronary artery disease

4. Require isolated CABG

5. LVEF ≥40 %

Exclusion criteria: 1. CABG with concomitant valvular procedures

2. CABG with concomitant repair of congenital heart disease.

3. Contra-indications to off-pump CABG or on-pump CABG (calcified aorta, intramuscular LAD, calcified coronaries, small target vessels, resection of ventricular aneurysm)

4. Severe congestive heart failure, New York Heart Association (NYHA) Class III or IV or pulmonary edema.

5. Chronic atrial fibrillation

6. Allergy to contrast material

7. Prior valve replacement or Redo CABG

8. Prior percutaneous coronary intervention (PCI) with stent implantation within 3 months
9. Concomitant medical disorders making clinical follow-up at least 3months unlikely or impossible e.g. neoplastic, hepatic, or other severe disease
10. Emergency CABG
11. LVEF \geq 39 %
12. Unable to give consent

Age minimum:

Age maximum:

Gender:

Health Condition(s) or Problem(s) studied

Multi-vessel Coronary Artery Disease

Intervention(s)

Intervention1: Off-Pump CABG: Beating Heart Surgery

Control Intervention1: On-Pump CABG: Heart Surgery on Cardiopulmonary Bypass

Primary Outcome(s)

The primary outcome is the assessment of Conventional coronary angiographic patency of the grafts at 3 months.-----Timepoint: The primary outcome is the assessment of Conventional coronary angiographic patency of the grafts at 3 months.

Secondary Outcome(s)

The secondary outcome is the occurrence of the composite of cardiovascular death, stroke, nonfatal MI, or new onset renal failure (AKI) requiring CRRT.-----Timepoint: At 3 months

Secondary ID(s)

NIL

Source(s) of Monetary Support

None

Secondary Sponsor(s)

Dr Gopichand Mannam

Dr Kunal Sarkar

Results

Results available:

Date Posted:

URL:

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