

ENROLLMENT AND RANDOMIZATION UPDATE

As of **December 8th**, there have been **4165** participants enrolled and **2462** randomized participants trial wide. India has enrolled **696** and randomized **391** participants.



Site Name	Enrolled	Randomized	Randomized CKD
All India Institute of Medical Sciences	53	32	4
Sree Chitra Tirunal Institute for Medical Sciences and Technology	3	2	0
Government Medical College	160	103	3
Ruby Hall Clinic	16	9	0
Sri Jayadeva Institute of Cardiovascular Sciences and Research	113	61	2
Jawaharlal Institute of Postgraduate Medical Education and Research	5	2	0
Ram Manohar Lohia Hospital	92	49	0
Hero DMC Heart Institute Unit Dayan and Medical	58	33	0
Gurunanak CARE Hospital	27	10	0
King George Medical University	34	17	0
Apollo Hospitals	29	16	0
Fortis Escorts Heart Institute	42	23	1
KEM Hospital	31	16	2
Apollo Health City Campus	10	7	0
MOSC Medical College Hospital	17	10	4
Fortis Healthcare Fl.t Lt. Rajan Dhall Hospital	1	0	0
CARE Hospital (Banjara Hills)	4	1	0
CARE Nampally	1	0	0

★ **InForm** ★
Enter data from completed visits within 5 days of the visit.

★ **Cardiac Markers** ★
Enter pre and post procedure cardiac marker data into InForm, as well as cardiac markers collected at AND in between other visits.

★ **Imaging** ★
Please remember to include stress worksheets and clinical reports when uploading stress tests. They can be attached to the uploaded images, in BioClinica Webview.

Top 5 Randomizing Countries

Country	Randomized
USA	489
India	391
UK	278
Canada	248
Brazil	173

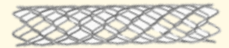
The ISCHEMIA Clinical Coordinating Center

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Mailbox: ischemia@nyumc.org
Website: www.ischemiatrial.org
US Helpline: 1-877-965-4877
(Physician on call for urgent matters)
See [Manual of Operations](#) for Country Specific Helpline Numbers)

Congratulations to Sites Newly Activated for Enrollment for ISCHEMIA

- ◇ MOSC Medical College Hospital, - (PI) Mathew, Anoop
- ◇ Fortis Healthcare Fl.t Lt. Rajan Dhall Hospital—(PI) Kaul, Upendra)
- ◇ CARE Hospital (Banjara Hills) —(PI) Christopher, Johann
- ◇ CARE Nampally- (PI) Christopher, Johann

Optimal Revascularization (ORT)



- Remember to use drug eluting stents (preferably Xience and Endeavor Resolute). Bare metal stents should not be used unless there is a compelling reason.
- Obtain cardiac markers (both CK-MB and Troponin) at 8 to 16 \pm 2 hours post PCI or at hospital discharge; at 18 \pm 6 hours post-CABG. All pre and post-procedure biomarker measurements that are obtained should be recorded on eCRF.
- Perform ECG at 60 \pm 30 minutes post-PCI and as needed for chest pain; within day 3 post-CABG and as needed for chest pain.
- Aim for complete functional revascularization with PCI.
 - * Revascularize territories with severe stenosis subtending areas of ischemia on non-invasive testing.
 - * Revascularize other areas with severe stenosis or abnormal FFR even if the non-invasive testing did not show ischemia.
 - * Chronic total occlusion (CTO) subtending areas that may be viable should be revascularized even if the collaterals are robust.
- Use arterial grafts liberally in patients undergoing CABG. At least a LIMA graft to the LAD is recommended.
- Record any post procedure persistent chest pain.
- Use heart team approach for left main or 3-vessel disease or whenever in doubt

ORT Problem Areas



Proportion of Patients Randomized to INV Undergoing Cath is Not 100% (Goal ~100%)

- All patients who are randomized to INV should undergo cath if no recent diagnostic cath was performed
- Schedule catheterization as soon as participant is enrolled, and randomize closer to the "scheduled" catheterization date
- Not enroll patients who are reluctant to undergo cath

Proportion of Patients Randomized to INV Undergoing Revascularization is Low (Goal ~90%)

- If patient refuses CABG, offer PCI with the goal of complete ischemic revascularization
- For angiographic non-obstructive disease, please perform FFR

Proportion of Patients Randomized to INV With Complete Revascularization is Low

- Goal of the trial is complete functional revascularization
- Consider CABG especially with CTO's and those with high SYNTAX score
- Revascularize territories with severe stenosis subtending areas of ischemia on non-invasive testing
- Revascularize other areas with severe stenosis or abnormal FFR even if the non-invasive testing did not show ischemia
- CTO subtending areas that may be viable should be revascularized even if the collaterals are robust

RECRUITMENT TIPS FOR ISCHEMIA-CKD

AS OF DECEMBER 7TH, 163 PATIENTS HAVE BEEN RANDOMIZED INTO ISCHEMIA-CKD WITH 16 IN INDIA

Establish workflow with your nephrologist

Creating a work flow where the nephrologist refers patients for stress test on clinical grounds and cc study coordinator to follow up on the results will help.

Look back at a list of dialysis and CKD patients

Check if they had any abnormal stress test within the year. CKD patients tend to be medically managed and can be enrolled. If a patient is identified using this approach, please remember to get approval from the CCC to enroll a patient with stress test >90 days old prior to enrollment.