

ISCHEMIA Trial Update

(As of April 29, 2016)

Enrolled

Worldwide: 5022
Asia-Pacific: 81

Randomized

Worldwide: 2958
Asia-Pacific: 48



ISCHEMIA-CKD Update

Enrolled

Worldwide: 271
Asia-Pacific: 3

Randomized

Worldwide: 261
Asia-Pacific: 3

ISCHEMIA World Cup

The World Cup competition has started! The scores for each round will be based on country performance using three criteria:



- Randomization rate
- Optimal Revascularization Therapy Compliance
- Female Enrollment rate

Visit www.ischemiatrial.org to find out more about the rules of the

**Green Lane
Coordinating Center**
Regional Leader
Prof. Harvey White

Clinical Trials Manager
Caroline Alsweller

**ISCHEMIA
Clinical Coordinating Center**

Website: www.ischemiatrial.org

Email: ischemia@nyumc.org

Phone: +1-212-263-4225

Fax: +1-646-754-9621

Regional Team
Alexandra Brackenheimer
Kevin Chan
Michelle Yee

Clinical Toll-Free Help Lines

New Zealand: 0800445642

Singapore: 8004481434

Taiwan: 108007440190

Thailand: 0018004414723

A Note from the CCC/GLCC Team...

We extend our deepest gratitude for the continued support from the amazing study teams in the Asia/Pacific Region. We have seen increased recruitment activity from your teams in the recent months and we hope to continue this success. We sincerely appreciate your ongoing efforts and look forward to our continued collaboration to expand the knowledge of ischemic heart disease.

Thank you



Screening Tips and Reminders!

What can I tell my colleagues who do not support the trial?



- CCTA (performed in majority of participants) excludes LM prior to randomization
- CON participants have close follow-up and can be sent to cath if their quality of life is not acceptable despite maximal medical therapy
- If participating in donation program, stents (Xience or Resolute) are available at no charge for INV participants
- Evidence suggests that it is ethical to randomize stable patients with moderate or severe ischemia to a conservative strategy
- There are nearly 3000 randomized participants! A Data and Safety Monitoring Board (DSMB) monitors the safety of the trial on a regular basis and has recommended to continue the trial!



Increasing awareness of the ISCHEMIA trial and its rationale will help physicians feel more comfortable with the study. Contact the ISCHEMIA CCC for physician materials or support for a local meeting at your site.

What if I am not seeing any stress tests with at least moderate ischemia?

- Speak with imaging physicians about the study. Ask them to contact you if there is an eligible patient
- Screen cases at stress labs as often as possible
- Ask imaging labs to inform referring physicians about the trial when notifying them about results showing at least moderate ischemia
- Identify other cardiologists or primary care physicians who are willing to screen their own patients and refer to your site for enrollment—they can manage the care of their own patients and collaborate with the study team to ensure study requirements are fulfilled

Screening for ISCHEMIA-CKD?

Patients with CKD tend to not present with chest pain and are frequently under-tested and under-treated. Identifying a nephrologist will help improve referral of this cohort of patients for stress testing and maximize enrollments for the ancillary study.

Data Collection During Follow-Up Period

Follow-Up Period Expectations

If a scheduled in-clinic visit is not possible, please try to collect data via:

- Telephone or email
- Review of electronic health record or public records
- Communication from a personal physician, allied health professional, or family member



How can I complete follow-up visits?

- M1.5, M3 & M12: Clinic visits
- M6, M18 & M30: Clinic or Telephone
- After M36: Clinic visits at least every 12 months

When should I collect QOL Questionnaires?

- Full Baseline: Rand Visit
- Brief Symptoms: M1.5 Visit
- Full Follow-Up: M12, M24, M36, etc.
- Brief Follow-Up: M6, M18, M30, etc.

Optimal Revascularization Therapy Reminders

Tips to ensure adherence to assigned INV strategy:

Before randomization:

- Remind participant (and family members) that both strategies are standard of care.



Do not randomize until all doubts are resolved.

- Randomize close to the time that cath/revascularization can be scheduled/performed.

After randomization:

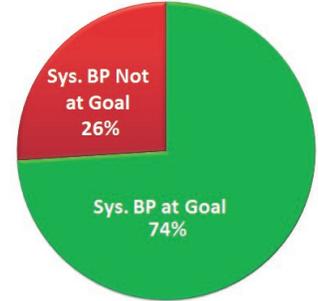
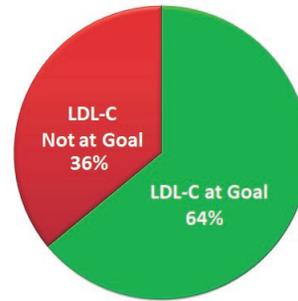
- Schedule cath as soon as possible.** Ideally, the time from randomization to cath should be 1-2 days.
- If a participant refuses the protocol-assigned cath, engage their personal physician to help. Cath and revascularization that is performed later is much better than not performed ever.

When should I collect cardiac markers?

- Pre procedure
- Post PCI/CABG procedure and attempted PCI
 - PCI cardiac markers should be collected 8-16 ± 2 hours or at hospital discharge, whichever comes earlier
 - CABG markers should be collected 18 ± 6 hours for participants undergoing CABG
- All available marker values should be recorded (i.e. if markers are “trended”, they should all be recorded in eCRF)
- Refer to MOO Section 3.7 for details about cardiac markers

Optimal Medical Therapy Reminders

To ensure participants meet trial definitions of optimal medical therapy, please review the monthly OMT reports and refer to the reminders and recommendations included in the reports.



- A majority of participants in the Asia/Pacific region met the LDL-C and Sys. BP goal at their last follow up visit.
- If you have any questions relating to OMT risk factors, goals, or therapies, please contact the ISCHEMIA CCC at ischemia@nyumc.org.

Our thanks to all study teams for your ongoing efforts to meet OMT goals.

Regional Study Teams

Site Name	Enrolled	Randomized
Waikato Hospital , New Zealand Dr. Gerard Devlin, Jayne Scales, Kirsty Abercrombie	27	17
Auckland City Hospital , New Zealand Dr. Ralph Stewart, Leah Howell	6	4
National Heart Centre Singapore , Singapore Dr. Terrance Chua, Min Tun Kyaw	6	5
Tan Tock Seng Hospital , Singapore Dr. David Foo, Cathy Li, Geraldine Tan, Zulaikha Ali, Noriza Mustapa, Xin Ni Koo	9 (+1 CKD)	6 (+1 CKD)
National University Heart Center , Singapore Dr. Kian Keong Poh, Vion Tan, Winnie Sia, Ying Ming Lee	16 (+2 CKD)	8 (+2 CKD)
Mackay Memorial Hospital , Taiwan Dr. Chung-Lieh Hung, Dr. Chun-Ho Yun, Yi-Hsuan Yang, Yu-Yao Fang	12	5
Chiang Mai University Hospital , Thailand Dr. Srun Kuanprasert, Warangkana Mekara, Supatchara Khwakhong, Supap Kulthawong	2	2
Ramathibodi Hospital , Thailand Dr. Sukit Yamwong, Pachara Panpunuan	3	1
Institut Jantung Negara , Malaysia Dr. Ahmad Khairuddin, Ling Ling Lim, Humayrah Hashim, Suahana Harip	0	0