ISCHEMIA Japan Update

National Heart, Lung, and Blood Institute

INTERNATIONAL STUDY OF COMPARATIVE HEALTH EFFECTIVENESS WITH MEDICAL AND INVASIVE APPROACHES

NYU Cardiovascular Clinical Research Center — Spring 2016

ISCHEMIA Trial Update

(As of April 29, 2016)

Enrolled
Worldwide: 5022
Japan: 16

Randomized:
Worldwide: 2958
Japan: 10

Message from your Country Leader

Greetings! There has been a great progress in our enrollment during the last 3 months. The study will continue enrollment until December 2017 and now aims for approx. 5,000-6,000 patients (2958 patients at present). There has also been a special interest in recruiting women; our goal is 35%, but only 22% of randomized participants are women.

With 20 months of enrollment to go, continued collaboration with the ISCHEMIA trial is much appreciated! Looking forward to seeing you all in future meetings.

Regards,
香坂 俊 / Shun Kohsaka

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 contest!

Please feel free to contact the CCC with any questions relating to patient eligibility, follow-up visits, data entry in InForm, etc.

Country Leader
Dr. Shun Kohsaka

ISCHEMIA Clinical Coordinating Center
Phone: 212-263-4225
Fax: 646-754-9621
Email: ischemia@nyumc.org

ISCHEMIA CCC Regional Team
Alexandra Brackenheimer
Kevin Chan
Michelle Yee

Websites:
www.ischemiatrial.org
www.ischemiackd.org

Japan Toll-Free Clinical Helpline:
00531440085

A Great Start to 2016!

Since January, the teams in Japan have randomized 4 participants and we look forward to more randomizations this year. We sincerely thank you for the hard work and appreciate all of Japan's contributions to the ISCHEMIA trial!

Enrollment Tips!

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

- Speak with imaging physicians—ask them to contact you if there is an eligible patient
- 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

How can I convince interventionalist colleagues to support the study?

- If high risk patients are not included, the outcome of ISCHEMIA may be negative as a result of referral bias
- Results of this trial will have long-lasting impact on interventional practice, including reimbursement
- Impact on cath lab volumes will be minimal as half of the participants are randomized to INV
- There is a safety net for participants randomized to CON arm to crossover for symptoms despite maximal tolerated medical therapy

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.

Study Teams in Japan

Site Name	Enrolled	Randomized
Keio University Hospital, Tokyo Dr. Keiichi Fukuda, Dr. Shun Kohsaka, Ikuko Ueda	8	5
National Cerebral and Cardiovascular Center, Osaka Dr. Satoshi Yasuda, Dr. Toshiyuki Nagai, Akemi Furukawa, Kanae Hirase	4	3
Saitama Medical University, Saitama Dr. Shigeyuki Nishimura, Dr. Shintaro Nakano	4	2