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 — December 2015

Screening Tips

- Ask imaging physicians to contact you if there is an eligible patient
- Post a pre-screening log in the stress lab for staff to fill in daily
- Go to the stress lab every day and read reports to find cases
- Ask the imaging attending to inform referring physicians about the trial when notifying them about results showing moderate or severe ischemia

Once a patient is identified…

- Call the referring physician and ask for permission to contact the patient
- Site staff must not contact pre-screened patients directly (unless they provide care to that patient)

Reminder! Active sites should submit **screening logs** the first Monday of every month by email (ischemia@nyumc.org) or fax (+1-646-754-9621). Include all patients with at least moderate ischemia. Please remember to **not** use any patient identifiers such as initials and date of birth.

Country Leader

Dr. Shun Kohsaka

ISCHEMIA Clinical Coordinating Center

http://ischemiatrial.org
Email: ischemia@nyumc.org
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ISCHEMIA CCC Regional Team

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Toll-Free Help Line

Japan 0367439064/00531440085

Message from your Country Leader

I look forward to continued PI support from all sites on this very important trial which has already become the LARGEST randomized controlled strategy trial ever conducted in patients with stable ischemic heart disease, exceeding BARI 2D and COURAGE. Please continue to promote the trial by speaking with referring physicians and at grand rounds (slide set can be provided).

皆様いつも ISCHEMIA 試験にご協力の程ありがとうございます。お陰様で日本でもゆっくりながらも確実な歩みをみせております。残りの期間もわずかとなりましたが、どうか宜しくお願い致します。

- Dr. Shun Kohsaka

Congratulations and Happy New Year!

As of **November 30**, there are **2427** participants randomized in ISCHEMIA and **157** participants randomized in ISCHEMIA-CKD.

Enrolling Sites in Japan

Site Name	Non Invasive PI	Interventional PI	Study Coordinator(s)	Enrolled	Randomized
Keio University Hospital, Tokyo	Keiichi Fukuda Shun Kohsaka	Aiko Kawamura	Ikuko Ueda	7	4
National Cerebral and Cardiovascular Center, Osaka	Satoshi Yasuda Keisuke Kiso	Junjiro Kobayashi	Akemi Furukawa Kanae Hirase Toshiyuki Nagai	1	1
Saitama Medical University, Saitama	Shigeyuki Nishimura	Jun Tanno	Shintaro Nakano	2	1

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

Follow-Up

- 1.5M, 3M & 12M: In clinic visits
- 6M, 18M & 30M: In clinic, Telephone, Email
- After 36M: should include clinic visits at least every 12 months

QOL Forms

- Full Baseline Questionnaire: Rand Visit
- Brief Symptoms Questionnaire: 1.5M Visit
- Full Follow-Up Questionnaire: 12M, 24M, 36M, etc.
- Brief Follow-Up Questionnaire: 6M,18M, 30M, etc.

Data Collection During Follow-Up Period (every visit)

- Visit Completion Status Form
- Visit Control Form
- Medical Status Assessment (BP, HR, weight)
- Medication Review
- Standard Laboratory Results (except 1.5M)
- QOL
- PACE Lifestyle Assessment –12M, Closeout
- Morisky Medication Compliance –12M, Closeout
- ECG –12M, 24M, Closeout
- Hospitalizations and/or extended care
- Procedures –cath, PCI, CABG
- Cardiac Markers
- Clinical Events

Reminder! **OMT and InForm Data Reports (All Exceptions and Core Lab Query) are sent to all sites on a monthly basis. Please review them and take appropriate action. If you have any questions, please do not hesitate to contact us.**