

Israel Update



National Heart, Lung, and Blood Institute

December 2015

INTERNATIONAL STUDY OF COMPARATIVE HEALTH EFFECTIVENESS WITH MEDICAL AND INVASIVE APPROACHES

NYU Cardiovascular Clinical Research Center

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 prescreened 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 Leaders Tali Sharir Rafael Beyar

Country Coordinator Eugenia Nikolsky

ISCHEMIA-CKD Country Lead Nephrologists Etty Kruzel

ISCHEMIA

Clinical Coordinating Center http://ischemiatrial.org Email: ischemia@nyumc.org Phone: +1-212-263-4225 Fax: +1-646-754-9621

ISCHEMIA CCC Regional Team Veronica Rowland

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Toll-Free Help Line Israel: 1809 444 701

Message from your Country Leaders

I look forward to your continued support 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. We would like to see this trial completed soon and it depends on your involvement and support. We believe that this trial may become a major source of information for clinical decisions in patients with stable CAD in the future.

Please continue to promote the trial by speaking with referring physicians and at grand rounds. We would strongly encourage you to intensify statin therapy with atorvastatin or rosuvastatin to the maximally tolerated dose for the best clinical effect for all the patients. Consider using dual antiplatelet therapy in all participants as long as the bleeding risk is not prohibitive. We value your participation and look forward to the near completion of the patient recruitment phase.

-Drs. Beyar and Sharir

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 Israel					
Site Name	Non Invasive PI	Interventional PI	Study Coordinator(s)	Enrolled	Randomized
Assuta Medical Centers, Tel Aviv	Tali Sharir	Dan Elian	Tali Gavra	12	9
Rambam Medical Center, Haifa	Arthur Kerner Samia Massalha	Ariel Roguin	Margalit Bentzvi Ludmila Helmer	7	4



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 Period

- 1.5M, 3M & 12M: In clinic visits
- 6M, 18M & 30M: In clinic, Telephone, Email
- After 36M: In clinic annually

QOL Forms

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

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 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 I 2M, 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.