ISRAEL UPDATE

ISCHEMIA

National Heart, Lung, and Blood Institute

INTERNATIONAL STUDY OF COMPARATIVE HEALTH EFFECTIVENESS WITH MEDICAL AND INVASIVE APPROACHES

NYU Cardiovascular Clinical Research Center

Autumn 2016

Study Updates as of 26 Sep 2016

Global Enrollments: 5760

Global Randomizations: 3413

CKD Randomizations: 350

Enrollment in the main trial will end in **December 2017**. With the end of the trial in sight, we need your help to reach our randomization target!

Country Leader

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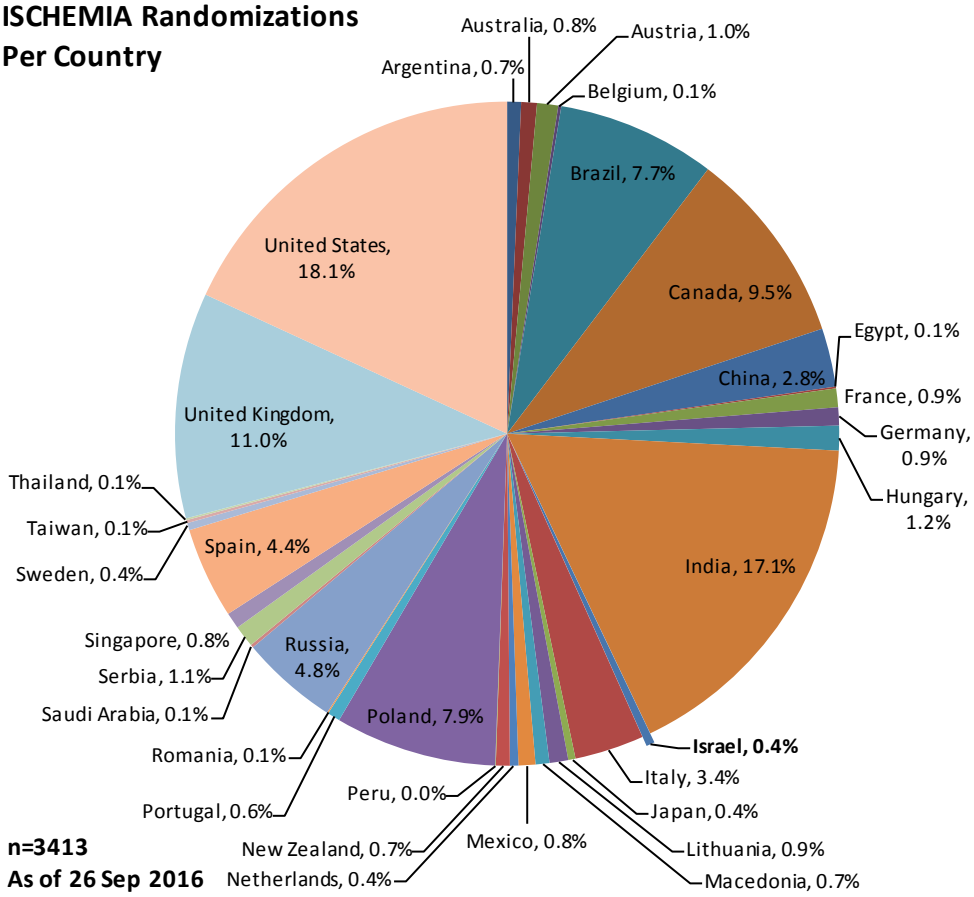
www.ischemiatrial.org

www.ischemiackd.org

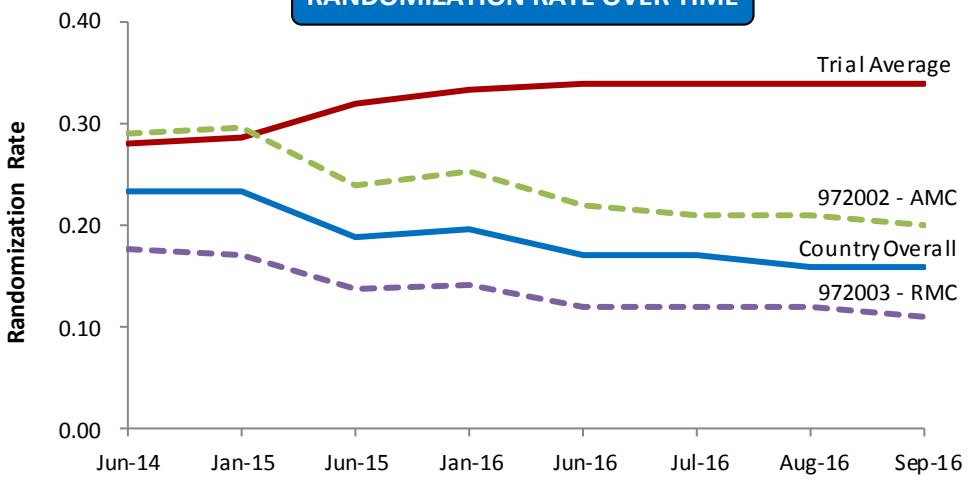
ALMAC Clinical Helpline

0800 295969 or 0120 609 1991

ISCHEMIA Randomizations Per Country



RANDOMIZATION RATE OVER TIME



Enrolling Sites in Israel	Enrollments	Randomizations
Assuta Medical Centers, Tel Aviv Dr. Tali Sharir, Dr. Dan Elian, Tali Gavra, Jasmine Shoham Marian	13	9
Rambam Medical Center, Haifa Dr. Arthur Kerner, Dr. Samia Massalha, Dr. Ariel Roguin, Margalit Bentzvi, Ludmila Helmer	9	5

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What if I am not sure about the level of ischemia?

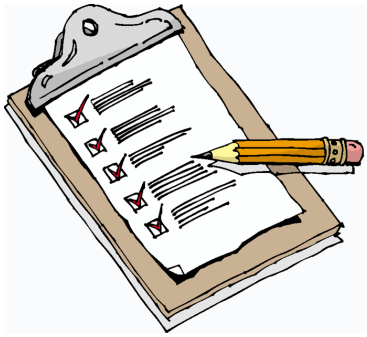
All sites may enroll patients based on their local core lab finding of moderate ischemia as long as all other eligibility criteria are met. If you would like to confirm that your site's interpretation of the amount of ischemia matches the core lab interpretation prior to enrollment, you may send anonymized stress images for core lab verification before trial consent or enrollment, if permissible by your local IRBs/ECs and privacy boards. This is called pre-enrollment verification.

Stress images (NUC/ECHO/CMR) may be submitted via BioClinica. For pre-enrollment verification of an ETT, please send the technical worksheet and de-identified tracings to the ISCHEMIA CCC in a SendSafe email. Please see Section 9.1.1 of the **MOO** for additional details.

1. Assign a temporary participant ID number with the six-digit site ID and a three digit "-800" or "900" number (e.g. 972001-801)
2. If transmitting stress images via BioClinica, select "Pre-enrollment ISCHEMIA" or as the Timepoint. Please remember to select "Expedited" reading
3. The CCC will email your site with the core lab interpretation. If all eligibility criteria are met, proceed with consenting and enrolling the participant
4. Notify the CCC of the participant ID assigned by ALMAC IXRS. The CCC will re-label the stress images (or ETT) with the new ID

Follow-Up Visits

Participant retention and follow-up is very important for the integrity of the trial results, in addition to ensuring the best care for treatment of ISCHEMIA. Reasonable efforts must be made to ensure that participants are being followed-up to confirm their adherence to medical therapy, assess their clinical status, and capture any hospitalizations or clinical events.



Semi-annual in-clinic visits are preferred, but please ensure to collect data via:

- Telephone or email
- Review of medical records from other care providers
- Communication from a personal physician, allied health professional, or family member

How flexible are the visit windows? What if my participant's visit is early or late?

- ✓ Please use the **Study Visit Scheduler** to help you plan future visits.
- ✓ Please note: If greater than 105 days has passed between enrollment and randomization, the participant will have to be screen failed in Almac IXRS and re-enrolled under a new participant ID.

Please notify the ISCHEMIA CCC if late visits are expected.

Let's Work Together!

If sites in Israel randomize **at least 1 participant per month**, Israel will surpass its randomization goal for the ISCHEMIA trial for the year!