HUNGARY 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 19 Sep 2016

Global Enrollments: 5728

Global Randomizations: 3399

CKD Randomizations: 345

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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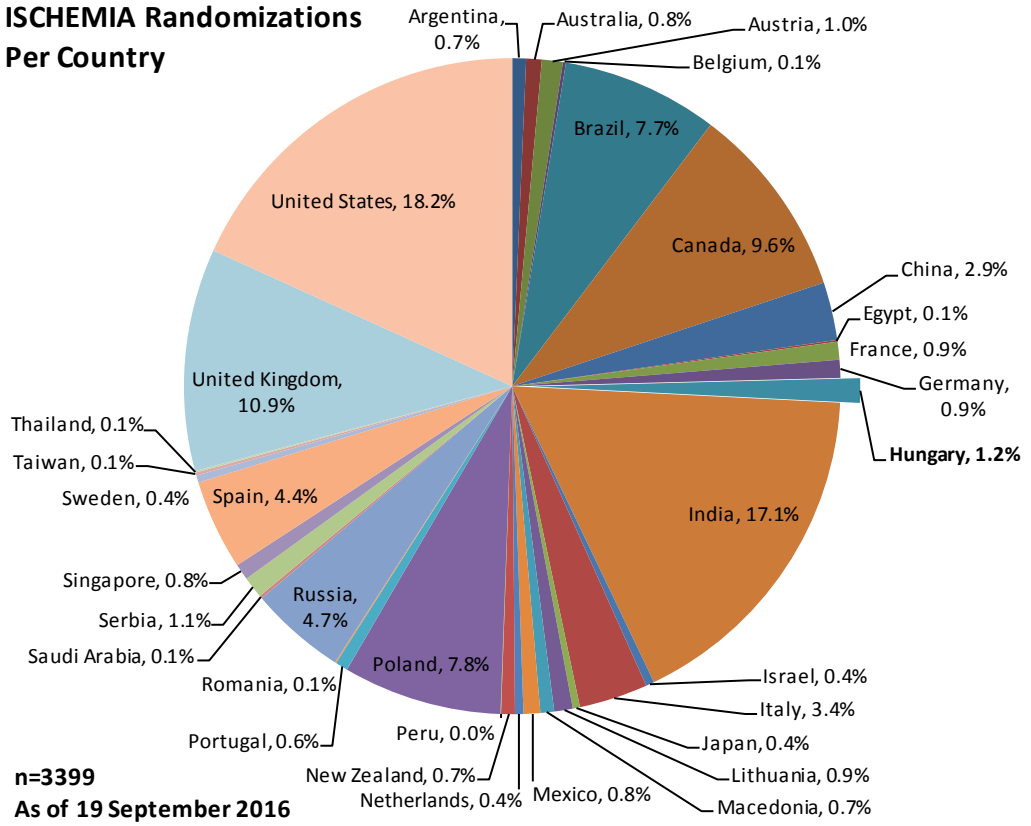
ALMAC Clinical Helpline

06 80 981 338

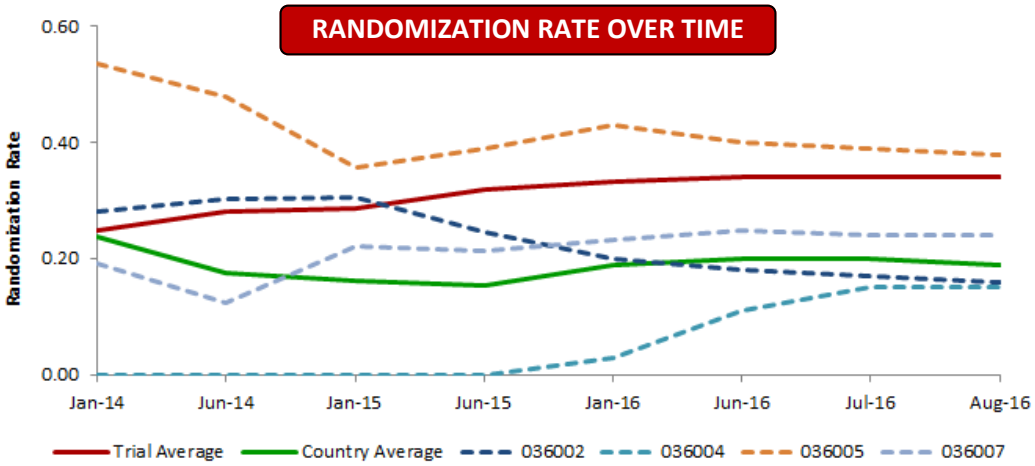
ISCHEMIA Randomizations Per Country



n=3399

As of 19 September 2016

RANDOMIZATION RATE OVER TIME



Enrolling Sites in Hungary	Randomizations: Main Trial	Randomizations: CKD
036005—Szent István Hospital, Budapest Dr. András Vértes, Dr. Géza Fontos, Dr. Zoltan Davidovits, Dr. Judit Sebo, László Matics	17	6
036007—University of Szeged, Szeged Prof. Albert Varga, Dr. Imre Ungi, Dr. Gergely Ágoston	10	—
036002—Semmelweis University, Budapest Prof. Béla Merkely, Dr. Andrea Bartykowszki, Dr. Pal Maurovich-Horvat	7	1
036004—Gottsegen György National Institute of Cardiology, Budapest Prof. Péter Andréka, Dr. Géza Fontos, Dr. Gábor Dékány	6	—

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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 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 (for example, 036002-801)
2. If transmitting stress images via BioClinica, select "Pre-enrollment ISCHEMIA" or "Pre-Enrollment CKD ISCHEMIA" as the Timepoint. 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

Core Lab Verification

The ISCHEMIA Clinical Coordinating Center may have notified you that core lab verification is required for specific stress test modalities at your site prior to CCTA (or randomization, if a study CCTA is not expected for a particular participant).

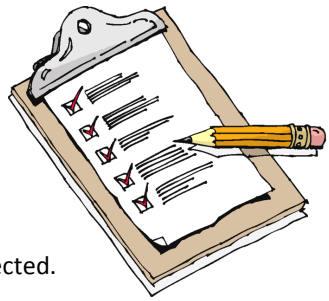
For Example

If core lab verification is required for participants enrolled with stress nuclear testing, please wait for a qualifying stress read (Moderate or Severe) to be entered in the SITEDATA form in InForm before proceeding with the CCTA (or randomization, if CCTA will not be done).

If you are not sure whether a participant's stress test will require core lab review, please contact the ISCHEMIA CCC. If core lab verification is not required, participants may proceed with the CCTA (or randomization) with a local lab report that indicates the participant has at least moderate ischemia. Eligibility criteria for each stress test modality are detailed in Section 3.3.1 in the **Manual of Operations**.

Follow-Up Visits

Participant retention and follow-up is important for the integrity of the trial results, in addition to ensuring the best care for treatment of SIHD. 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 data may be collected via:

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

Our **Study Visit Scheduler** can help you plan future visits. Please notify the ISCHEMIA CCC if late visits are expected.

Let's Work Together!

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