ISCHEMIA FRANCE UPDATE

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

Country Leader

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Country Coordinators:

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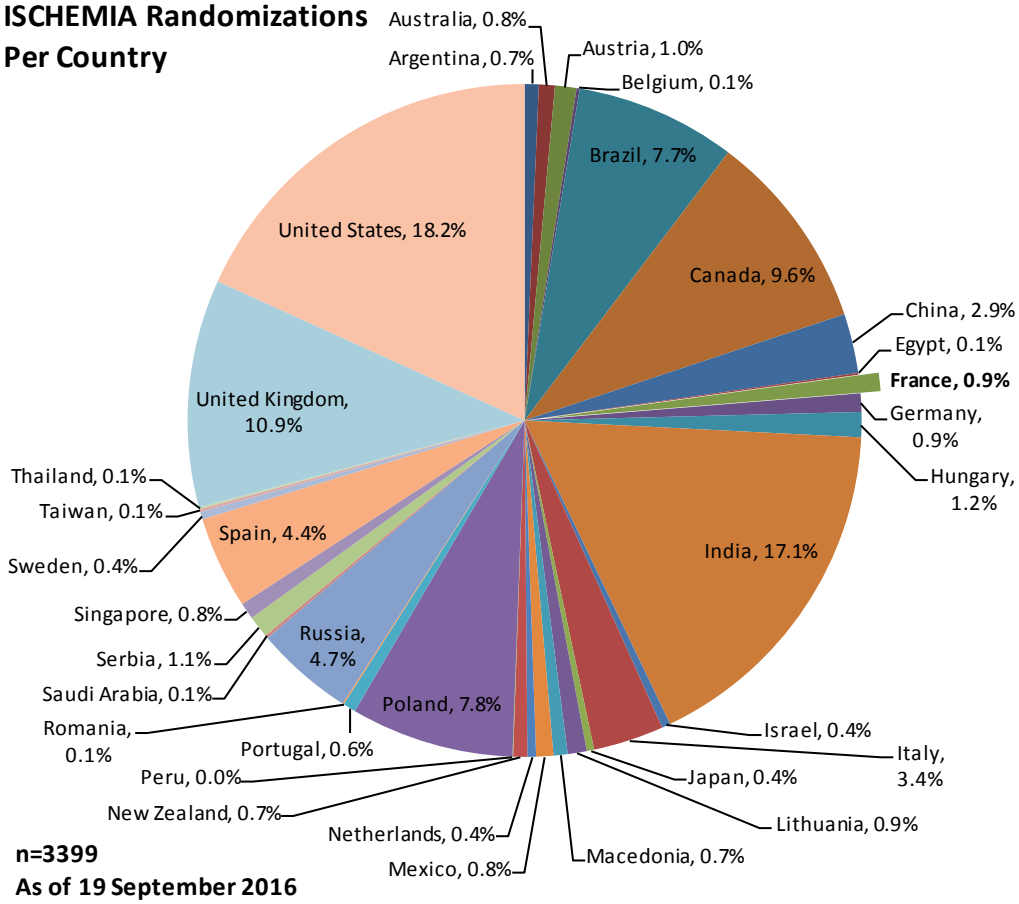
ALMAC Clinical Helpline

0800 918621

ISCHEMIA Randomizations Per Country



n=3399
As of 19 September 2016

Let's Work Together!

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

Enrolling Sites in France	Randomizations	
	Main Trial	ISCHEMIA-CKD
Centre Hospitalier Louis Pasteur, Chartres Dr. Christophe Thuaire, Christophe Laure, Emilie Tachot, Corine Thobois, Dr. Téodora Dutoiu	12	1
Hôpital Bichat-Claude Bernard, Paris Pr. Philippe Gabriel Steg, Helene Abergel, Axelle Fuentes	8	2
Hôpital Antoine-Béclère, Clamant Pr. Michel Slama, Dr. Ludivine Eliahou	4	—
Centre Hospitalier Sud Francilien, Corbeil-Essonnes Dr. Eric Nicollet, Patricia Brito, Pascal Goube	2	—
Centre Hospitalier Universitaire de Grenoble, Grenoble Dr. Gilles Barone-Rochette, Clémence Charon	2	—
Hôpital Ambroise-Paré, Boulogne-Billancourt Dr. Rami El Mahmoud, Pr. Olivier Dubourg, Dr. Pierre Michaud	1	—
Centre Hospitalier Universitaire d'Angers, Angers Pr. Alain Furber, Charles Cornet, Jeremy Rautureau	1	—

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Engage your Colleagues

How can I optimize recruitment?

- ✓ Speak with imaging physicians—remind them to contact you if there is an eligible patient
- ✓ Ask imaging labs to remind referring physicians about ISCHEMIA if they find patients with at least moderate ischemia
- ✓ Identify other cardiologists or primary care physicians who are willing to screen and refer their own patients to your site

How can I convince interventional cardiologists to support the study?

- ✓ Including high risk patients will reduce the impact of referral bias on the outcome of ISCHEMIA
- ✓ Results of this trial will have a 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

What can I tell other colleagues at my site who do not support the trial?

- ✓ A Data and Safety Monitoring Board (DSMB) monitors the safety of the trial on a regular basis and has recommended the continuation of the trial.
- ✓ Evidence suggests that it is ethical to randomize stable patients with moderate or severe ischemia to a conservative strategy, with cath as needed
- ✓ CON participants are closely monitored in follow-up and can be sent to cath if necessary
- ✓ CCTA (performed in majority of participants) excludes participants with left main disease prior to randomization
- ✓ If your site is participating in the device donation program, stents (Xience or Resolute) are available at no charge for INV participants

Contact the ISCHEMIA CCC team for physician materials or support for a local meeting at your site.

Data Reminders

- ✓ Please prioritize requests from the Clinical Events Committee (CEC) and answer CEC queries in InForm promptly to expedite the event adjudication process.
- ✓ Enter data for participants as soon as possible after each follow-up visit or procedure.
- ✓ For a list of required assessments at each study visit, please refer to the Schedule of Assessments in the **MOO Appendix.**
- ✓ Remember to review open queries frequently. When logged into InForm, please click on 

in the sidebar. If further clarification is needed for any queries, please contact the ISCHEMIA CCC.

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.

Assign a temporary participant ID number with the six-digit site ID and a three digit "-800" or "900" number (for example, 033001-801)

If transmitting stress images via BioClinica, select "Pre-enrollment ISCHEMIA" or "Pre-Enrollment CKD ISCHEMIA" as the Timepoint. Select "Expedited" read

The CCC will email your site with the core lab interpretation. If all eligibility criteria are met, proceed with consenting and enrolling the participant

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