

STUDY UPDATES

Enrolled: 4905 | Brazil: 280
Randomized: 2897 | Brazil: 214

The ISCHEMIA World Cup has started

Let's WIN!

It's not all about football in Brazil!



The scores for each round will be based on country performance using three criteria:

- ⇒ Randomization rate
- ⇒ Optimal Revascularization Therapy Compliance
- ⇒ Enrollment Rate of Women

Visit www.ischemiatrial.org to find out more about the rules of the contest.

Let's set goals for Brazil for 2016!

Brazil has randomized 216 as of April 22nd, 2016.

Let's work together toward exceeding the projected target for Brazil by the end of 2016!

If sites in Brazil collectively randomize **at least 1 participant** per month, Brazil will surpass the randomization goals for the ISCHEMIA trial for the year.



Together we can do it!

If you have questions, please contact us:

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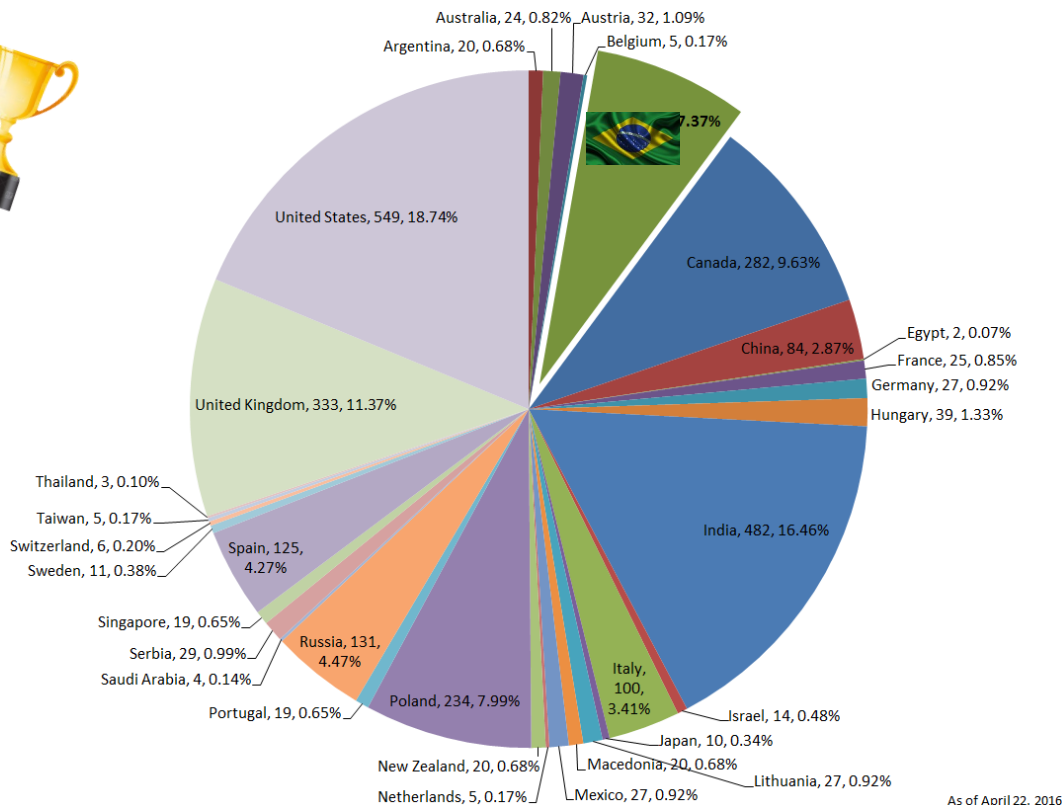
Email: ischemia@nyumc.org

COUNTRY'S ALMAC Clinical Helpline:

0800 891 9827

www.ischemiatrial.org www.ischemiackd.org

A LATE ENTRANT BRAZIL IS MORE THAN 7% OF THE PIE AND GROWING!



As of April 22, 2016

Thank you to all sites in Brazil for their continued hard work and dedication to the ISCHEMIA trial



CONEP HAS APPROVED THE ISCHEMIA-CKD AND THE CIAO-ISCHEMIA ANCILLARY STUDIES!

What can you do now to set you up for success in these studies:



Expands the pool of potential enrollees to include those with chronic kidney disease (eGFR <30 or on dialysis).

Patients with CKD tend not to present with chest pain and are frequently under tested and under treated. Identifying a nephrologist will help improve referral of patients for stress testing and maximize enrollments.



Enrolls participants excluded from ISCHEMIA due to no obstructive disease on the study CCTA, with a qualifying stress ECHO.

To facilitate future enrollments in CIAO, we recommend that you ask ISCHEMIA trial enrollees to complete the baseline QOLs at the time of enrollment or at the CCTA visit. By doing this, once you have approval for CIAO enrolling these patients will be easy!

The BCRI team will be working with you to help you with local ethics committee submissions. A training webinar for ISCHEMIA-CKD and CIAO-ISCHEMIA will be offered for sites in Brazil.

LET'S IMPROVE BRAZIL'S PERFORMANCE IN OPTIMAL MEDICAL THERAPY

Only approximately 31% of ISCHEMIA randomized participants in Brazil are at the trial's primary lipid goal of LDL-C <70mg/dl.

Please remember that the most efficient way to get participants to goal is by prescribing maximum dose high intensity statins, either rosuvastatin 40 mg or atorvastatin 80 mg. Then add ezetimibe if not at goal.



HOW TO IMPROVE OPTIMAL REVASCULARIZATION THERAPY (ORT) ADHERENCE?

MAXIMIZING ADHERENCE TO ASSIGNED STRATEGY IS CRITICAL!

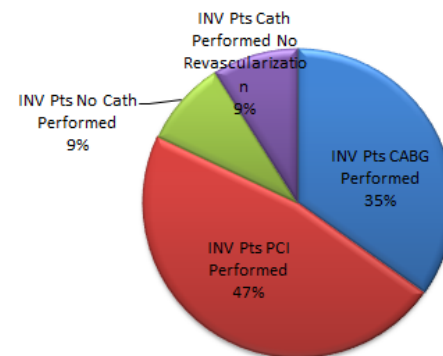
REMINDERS TO IMPROVE CATH ADHERENCE

BEFORE RANDOMIZATION:

- Remind participant (and family members) that both strategies are standard of care. **Do not randomize until all doubts are resolved.**
- Randomize close to the time that cath/revascularization can be scheduled/performed.

AFTER RANDOMIZATION:

- Schedule cath as soon as possible after randomization** and within a 30 day target. Ideally the time from rand to cath should be 1-2 days.
- If a participant refuses the protocol-assigned cath, engage their personal physician to help. Cath and revascularization performed late is much better than not performed ever.



ORT Performance in Brazil

REMINDERS TO MAXIMIZE REVASCULARIZATION ADHERENCE

TO INCREASE % UNDERGOING PCI & CABG

- For non-obstructive disease, perform FFR
- If patient refuses CABG, offer PCI with the goal of complete ischemic revascularization

TO INCREASE % WITH COMPLETE REVASCULARIZATION

- Use FFR liberally
- Favor CABG for high SYNTAX score and/or CTOs
- Revascularize territories with severe stenosis causing ischemia
- Revascularize other areas with severe stenosis or abnormal FFR even if the non-invasive testing did not show ischemia
- Revascularize viable areas supplied by CTO (even if collaterals are robust)

BRAZIL'S TOP RANDOMIZERS

INSTITUTION	PRINCIPAL INVESTIGATOR	ISCHEMIA RANDOMIZATIONS	ISCHEMIA RANDOMIZATION RATE
InCor-HCFMUSP Sao Paulo	Dr. Whady Hueb	69	3.38
Instituto Dante Pazzanese de Cardiologia Sao Paulo	Dr. Paola Smanio	50	2.31
Instituto de Cardiologia de Porto Alegre Porto Alegre	Dr. Alexandre de Quadros	22	0.95
Hospital das Clinicas FMRP-USP Ribeirao Preto	Dr. Jose Marin-Neto	16	0.70
Quanta Diagnostico e Terapia Curitiba	Dr. Joao Vitola	15	0.64

DRUG DONATIONS



Randomized ISCHEMIA Brazilian participants now have free access to **Vytorin 10/40mg** (Ezetimibe and Simvastatin) and **Zetia 10mg** (Ezetimibe).

Please contact the ISCHEMIA CCC for more information on how to order these medications.

Data Quality Awards

Congratulations! 3 sites in Brazil have been recognized for superior data quality during the past 6 months. In appreciation for study coordinator efforts, each site will receive a Certificate of Excellence and an Amazon.com gift eCertificate!

Dr. Joao Vitola
Sandra Zier

Quanta Diagnostico e Terapia

Dr. Jose Marin-Neto
Diego Franca da Cunha
Ana Silva

Hospital das Clinicas FMRP-USP

Dr. Whady Hueb
Priscila Borges Miyamoto Girardi

Myrthes Takiuti
Heart Instituto do Coracao - University of Sao Paulo

Congratulations

To Dr. Paola Smanio, study coordinator Leonardo De Pizzol and their study team from **Instituto Dante Pazzanese de Cardiologia in Sao Paulo** for randomizing their 50th participant.