

# REGIONAL NEWSLETTER LATIN AMERICA: MEXICO-ARGENTINA-PERU



INTERNATIONAL STUDY OF COMPARATIVE HEALTH EFFECTIVENESS WITH MEDICAL AND INVASIVE APPROACHES

NYU Cardiovascular Clinical Research Center

**APRIL, 2016** 

## **STUDY UPDATES**

Enrolled: 4905 Argentina: 27 Mexico: 47

Peru: 1

Randomized: 2897 Argentina: 20 Mexico: 27 Peru: 0

Ancillary Studies

CKD

Enrolled: 261

Argentina: 4 Mexico: 2

Peru: 0

Randomized 248
Argentina: 3 Mexico: 2
Peru: 0

CIAO

Enrolled: 75 | Latin America: 0\*
\*Argentina does not participate in the CIAO
ancillary study

# The ISCHEMIA World Cup has started!

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 <u>www.ischemiatrial.org</u> to find out more about the rules of the contest.

# ISCHEMIA Clinical Coordinating Center

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Websites:

www.ischemiatrial.org www.ischemiackd.org

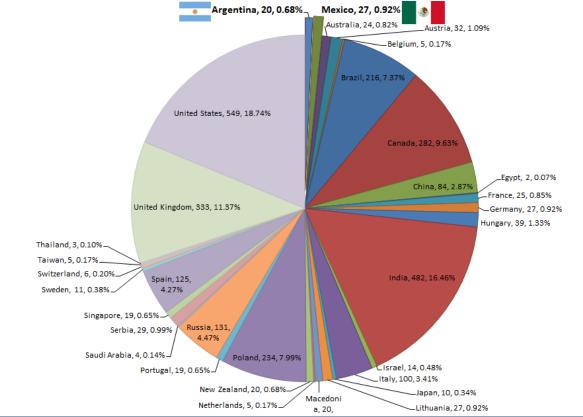
**ALMAC CLINICAL HELPLINE:** 

Argentina: 08006662209

Mexico: 018001234833

Peru: 800 52 847

Latin America's Randomizations and the World: You have potential for more!



## Here are some tips on how to improve enrollment:

#### CREATE AWARENESS

- □ Talk about ISCHEMIA during team meetings.
- Network with teams from local cardiologist & primary care physicians
- Campaign about trial rationale. Publications are available that justify the conduct of the trial.

The CCC can provide letters, slides and other materials to help your site.

SCREEN MULTIPLE STRESS LABS DAILY

DAILY Screening increases the likelihood of

recruiting the patient before a cath is sched-

⇒ Build a team to notify you when an eligi-

⇒ Have a system in place to communicate

⇒ Ask the lab to provide a list of patients

with the referring physician promptly

with stress images showing at least mod-

ble patient is recognized

### MONITOR CATH LABS

**GETTING INTERVENTION-**

ALIST SUPPORT

Check out and dissemi-

nate this video from Dr.

**Gregg Stone in support** 

of the study: http://

www.crf.org/

ischemia.html

Are patients with ischemia being immediately referred for cardiac cath? If possible, identify and talk to the referring physician(s).

# Remind them that:

prior to randomization

- CCTA (done in majority of participants) excludes LM
- CON participants have close follow-up & can be sent to cath if their quality of life is not acceptable despite maximal medical therapy

**GETTING REFERRING PHYSICIAN SUPPORT** 

A Data & Safety Monitoring Board monitors the trial

### EXPAND REFERRAL SOURCES

Have multiple referral sources to build your pool of eligible patients:

- Private practices affiliated with referring centers
- Multiple stress testing labs
- Other cardiologists, primary care physicians (they can continue to manage the clinical care of their patients while collaborating with study team)

ISCHEMIA can provide nominal reimbursement to cover for work done during pre-screening. Contact the CCC for more information.

## For ISCHEMIA-CKD:

erate ischemia

uled

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 for the ancillary study.

#### INTERNATIONAL STUDY OF COMPARATIVE HEALTH EFFECTIVENESS WITH MEDICAL AND INVASIVE APPROACHES

## **Drug Donations**



Randomized participants in Argentina and Mexico now have free access to the following medications to optimize their medical therapy:

## **ARGENTINA**

- ⇒Vytorin 10/40mg
- (Ezetimibe and Simvastatin)
- ⇒**Zetia 10mg**(Ezetimibe)

### **MEXICO**

- *⇒Crestor 20mg* (Rosuvastatin)
- ⇒ Brilinta 90mg (Tricagrelor)

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

## Congratulations

Dr. Jorge Escobedo and study coordinator Ramon de Jesus Perez from IMSS in Mexico hit a milestone of randomizing over 25 participants

Dr. Mariano Rubio and study coordinators Dr. Graciela Scaro and Sandra Beatriz Pelayes from **Clínica Privada Vélez Sarsfield** in Argentina randomized their first two participants to the ISCHEMIA-CKD ancillary study

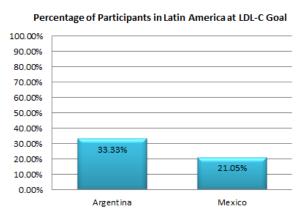
Dr. Dr. Carlos Alvarez and study coordinator Marina Garcia from Hospital Italiano Regional del Sur Bahia Blanca in Argentina enrolled their first ISCHEMIA-CKD participant

### LET'S IMPROVE LATIN AMERICA'S PERFORMANCE IN OPTIMAL MEDICAL THERAPY (OMT)

There is still some work to be done at Latin American sites to achieve the trial's primary lipid goal of LDL-C <70mg/dl for ISCHEMIA randomized participants.

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.

If you have any questions please contact the CCC Risk Factor Management Team at ischemia@nyumc.org



## LATIN AMERICA'S OPTIMAL REVASCULARIZATION THERAPY COMPLIANCE (ORT)

100%

### **MAXIMIZING ADHERENCE TO ASSIGNED STRATEGY IS CRITICAL!**

Congratulations to all of our sites in Latin America for excelling in percentage of performance of protocol assigned cath for INV participants.

# REMINDERS TO MAXIMIZE REVASCULARIZATION ADHERENCE

## To Increase % Undergoing PCI & CABG

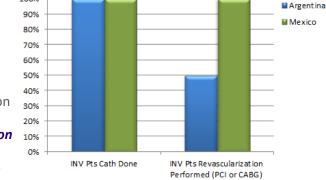
- ⇒ For non-obstructive disease, perform FFR
- ⇒ If patient refuses CABG, offer PCI with the goal of complete ischemic revascularization

## 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)

Please remember to have a copy of the ORT MOO (available at <a href="www.ischemiatrial.org">www.ischemiatrial.org</a>) at your cath lab/ CABG site as a resource for interventionalists and surgeons for technical details pertaining to PCI and CABG.

Note: If a cath or revascularization is not planned for an INV participant notify the CCC



LATIN AMERICA'S TOP RANDOMIZERS				
Institution	PRINCIPAL INVESTIGATOR	ISCHEMIA RANDOMIZATIONS	ISCHEMIA RANDOMIZATION RATE	ISCHEMIA-CKD RANDOMIZATIONS
IMSS Mexico City- Mexico	Dr. Jorge Escobedo	26	0.78	2
Fundacion Favaloro Buenos Aires- Argentina	Dr. Julio Figal	9	0.28	1
Instituto Medico DAMIC Córdoba- Argentina	Dr. Luis Guzman	6	0.18	0
Clínica Privada Vélez Sarsfield Córdoba- Argentina	Dr. Mariano Rubio	1	0.07	2