

# REGIONAL NEWSLETTER -SPAIN-



INTERNATIONAL STUDY OF COMPARATIVE HEALTH EFFECTIVENESS WITH MEDICAL AND INVASIVE APPROACHES

NYU Cardiovascular Clinical Research Center

APRIL, 2016

# **STUDY UPDATES**

Enrolled: 4907 | Spain: 202 Randomized: 2897 | Spain: 122

# **Ancillary Studies**

**CKD** Enrolled: 261| Spain: 5 Randomized: 248| Spain: 5

**CIAO** Enrolled: 75 | Spain: 12

The ISCHEMIA World Cup has started: Let's WIN!

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.

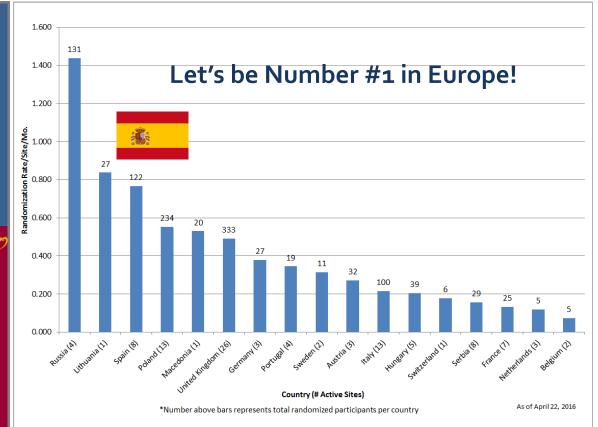
*If you have questions, please contact us:* 

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SPAIN's ALMAC Clinical Helpline: 900984477



Spain is in third place in Europe and fourth place worldwide in randomization rates for ISCHE-MIA.

YOU have the potential to make it the top country in Europe and perhaps the world!

# Setting goals for Spain for 2016!

Spain has randomized 122 as of April 21<sup>st</sup>, 2016. Our projected target for Spain by the end of 2016 is **184 participants**.

If each active site in Spain randomizes at least 1 participant per

month, Spain will achieve the randomization goals for the ISCHEMIA trial for the year.

Together we can do it!



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

# Data Quality Awards

Congratulations! 2 sites in Spain have been recognized for superior data quality during the past 6 months. In appreciation for their efforts, each site will receive a Certificate of Excellence and an Amazon.com gift eCertificate!

Dr. Francisco Marin Ana Romero **Esteban Orenes** Miriam Ginar Hospital Virgen de la Arrixaca

Dr. José Lopez-Sendón Virginia Fernandez-Figares Dr. Almudena Castro Dr. Silvia Valbuena Ainara Albaladejo Guiomar La Paz Mediavilla **Hospital Universitario La Paz** 

# Congratulations

To the following sites for randomizing their first ISCHEMIA participants:

Dr. Vincente Miró and Dr. Begoña Igual Muñoz from Hospital Universitario y Politecnico La Fe

Dr. José Gonzalez-Juanatey and José Seijas Amigo, Xurxo Martinez-Seara and Diana Pereiro from Hospital Clinico Santiago de Compostela

We wish you continued success!

## SPAIN'S PERFORMANCE IN OPTIMAL MEDICAL THERAPY (OMT)

Only approximately 46% of ISCHEMIA randomized participants in Spain 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.

46% If you have any questions please contact the CCC Risk Factor Management

#### How to IMPROVE OPTIMAL REVASCULARIZATION THERAPY (ORT) ADHERENCE IN SPAIN?

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

#### **Before randomization:**

Team at ischemia@nyumc.org

- Remind participant (and family members) that both strategies are standard of care. **Do not ran**domize 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. Ideally the time from randomization 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.

#### 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 liberallv
- ⇒ 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)

SPAIN' S TOP RANDOMIZERS					
INSTITUTION	PRINCIPAL INVESTIGATOR	ISCHEMIA RANDOMIZATIONS	ISCHEMIA RANDOMIZATION RATE	ISCHEMIA-CKD RANDOMIZATIONS	CIAO-ISCHEMIA ENROLLMENTS
Hospital Universitario La Paz -Madrid	Dr. José Luis Lopez- Sendón	74	2.36	5	12
Complejo Hospitalario Universitario de A Coruna- <i>A Coruna</i>	Dr. Jesus Peteiro	23	2.38	0	0
Hospital de Sant Pau Barcelona - Barcelona	Dr. Alessandro Sionis and Dr. Xavier Garcia Moll	11	0.36	0	0
Hospital Virgen de la Arrixaca - Murcia	Dr. Francisco Marin	7	0.30	0	0
Hospital de Bellvitge - Barcelona	Dr. Montserrat Gracida Blancas	4	0.14	0	0

INV Pts Cath INV Pts CABG Performed No Performed Revascularizatio 23% 14% INV Pts No Cath -Performed INV Pts PCI 5% Performed 48%

