

SPAIN UPDATE



INTERNATIONAL STUDY OF COMPARATIVE HEALTH EFFECTIVENESS WITH MEDICAL AND INVASIVE APPROACHES

NYU Cardiovascular Clinical Research Center

🚩 Autumn 2016

Study Updates

Global Enrollments: **5695** Spain Enrollments: **246**

Global Randomizations: **3397** Spain Randomizations: **151**

Global CKD Randomizations: **341** Spain CKD Randomizations: **5**

A Message from Dr. Lopez-Sendon

Quality is as (more!) important as the randomization number!

- Adherence to the protocol
- Data completion and submission
- Clean queries asap
- Retention
- Optimal medical therapy and optimal revascularization



Let's be the best!

Country Leader

Dr. Jose Lopez-Sendon

Email: <u>ilopezsendon@gmail.com</u>

CKD Country Leaders

Dr. Rafael Selgas Dr. Almudena Castro

ISCHEMIA CCC Regional Team

Alexandra Brackenheimer Diana Cukali Carly Pirro

ISCHEMIA Clinical Coordinating Center

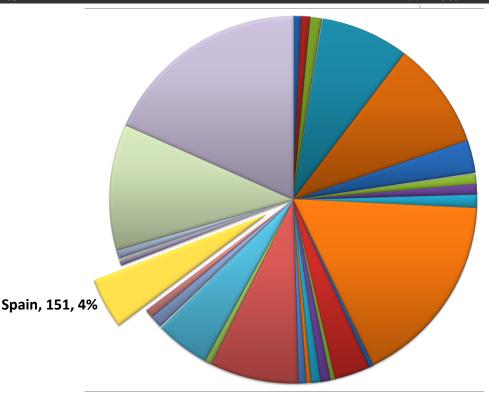
Phone: +1 212-263-4225 Fax: +1 646-754-9621 Email: ischemia@nyumc.org

Websites:

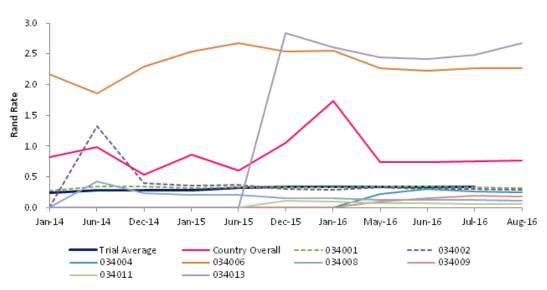
www.ischemiatrial.org www.ischemiackd.org

ALMAC Clinical Helpline

06950985571



RAND RATE OVER TIME



Top Three Randomizing Sites in Spain	Main Trial		CKD	
	Enrolled	Randomized	Randomized	
Site 034006—Hospital Universitario La Paz, Madrid Dr. Jose Luis Lopez-Sendon	123	83	5	
Site 034013—Complejo Hospitalario Universitario de A Coruna, A Coruna Dr. Jesus Peteiro	77	37	_	
Site 034001—Hospital de Sant Pau Barcelona, Barcelona Dr. Alessandro Sionis and Dr. Xavier Garcia-Moll	12	11	_	



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Common Questions and Concerns;

My participant's enrolling stress test is greater than 90 days old. What should I do?

✓ If a stress test was performed greater than 90 days prior to the date of enrollment, please contact the CCC.

How flexible are the visit windows? What if my participant's visit is early or late?

✓ Please use the study visit scheduler to help you plan future visits. See below for an example:

Randomized January 1st 2016

M6 Target: July 2nd 2016
Window <u>+</u> 6 weeks

M12 Target: Jan 1st 2017
Window <u>+</u> 6 weeks

Actual Visit: November 1st, which is closer to M12 visit. Enter info into M12 visit on InForm and mark M6 visit as "Not Done" but continuing in the study

Please note: If greater than 105 days has passed between enrollment and randomization, the participant will have to be screen failed in Almac IXRS and re-enrolled under a new participant ID.

How often should a lipid panel be performed?

✓ Lipid panels are required from the participant's physician and every 6 months thereafter:

Baseline 💙

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M12

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M24 (



- ✓ If the participant's LDL was at goal at the baseline/randomization visit, and no change in statin therapy has occurred, it is <u>not</u> necessary to repeat a lipid panel until the 6 month visit. In this case, check "Not done" on the VISITLAB eCRF form for M3
- ✓ Any time a change in statin therapy has occurred, lipid panels need to be performed



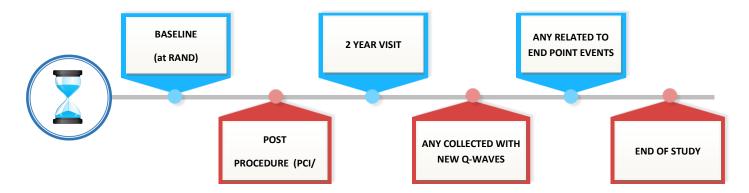
Let's Work Together!

If sites in Spain continue to randomize **at least 1 participant per month**, Spain will surpass its randomization goals for the ISCHEMIA trial for the year!

ECGs? Yes Please!



ECG collection at all required time points is crucial for analysis at the end of the study. It allows for a participant's progress in the trial to be tracked over time. ECGs must be labeled with the participant ID, visit name, date, and time. The following ECG time points should be submitted to the ECG Core Lab via BioClinica WebSend:



^{*1} year ECG is recommended but not required