

ISCHEMIA Update PORTUGAL



International Study of Comparative Health Effectiveness with Medical and Invasive Approaches

NYU Cardiovascular Clinical Research Center

Portugal November 2015



Some ISCHEMIA facts about our Portugal sites



Dr. Pinto and the staff at CHLN Hospital Santa Maria were first to be
activated in Portugal. The site has
enrolled and randomized the first
ISCHEMIA participant in the country!!

Dr. Ramos and staff at the
Hospital de Santa Marta have the
highest randomization rate amongst the
sites in Portugal—close to randomizing
one participant per month!

Dr. Abreu and the team at the
Hospital Fernando Fonseca have been
recently activated for the main
ISCHEMIA trial and are ready to enroll
their first participant for ISCHEMIA!

Please welcome our newest Portuguese site, Centro Hospitalar de Vila Nova de Gaia! Dr. Nuno Ferreira will be leading ISCHEMIA's 4th activated site in Portugal.

We thank the team from **Centro Hospitalar de Vila Nova de Gaia** for their help in getting their site ready for enrollment! We also look forward to welcoming Dr. Catarina Sousa and the team from **Centro Hospitalar Barreiro Montijo**!

They are in the process of activation and will be ISCHEMIA's 5th site in Portugal.



Enrolled: 4058 Randomized: 2404





ISCHEMIA SITE UPDATE	Enrolled	Randomized
Hospital de Santa Marta	17	7
CHLN - Hospital Santa Maria	5	3
Hospital Fernando Fonseca	0	0
Centro Hospitalar de Vila Nova de Gaia	0	0



Please send the completed technical worksheet via BioClinica when enrolling a participant via Stress Echo, CMR or NUC. This can be attached at the time of upload via WebSend, or at a later date via the

WebView portal(<u>www.websend.bioclinica.com</u>). The same process applies to the technical worksheet for CCTAs.

Please send the complete technical worksheet and the exercise ECGs from the qualifying stress test to the CCC via SafeSend when enrolling a participant via ETT.

CCTAs are required to be uploaded to Bioclinica; if you experience any issues during the upload please contact Bioclinica helpdesk for assistance HelpDeskMailbox@BioClinica.com

IMPORTANT OMT UPDATE!

OMT reports will be sent monthly. Please review the report to ensure your participants are meeting OMT goals. We strongly recommend contacting patients or their GPs to adjust medications as needed between visits.

Participants randomised to the INV strategy must have the diagnostic films, PCI films (if applicable), post procedure ECG, and a copy of the anonymized PCI or CABG report uploaded via BioClinica. Other required data, such as cardiac markers, must be entered directly into InForm.

ISCHEMIA Clinical Coordinating Center

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Portugal Clinical Helpline: (800)844-535



Portugal has enrolled and randomized 2 CKD patients
Dr. Ruben Ramos has 2 CKD Randomizations!

CKD Country Leader: Ruben Ramos Email: nebursomar79@yahoo.com.br Telephone: 351 963 156 910 Fax: 351 213 531 983

CKD Lead Nephrologist: Fernando Nolescu

Email: febnolasco@gmail.com
CKD Mailbox: ischemia@nyumc.org
CKD Website: www.ischemiackd.org
Portugal Helpline: (800)844-535

Non-protocol assigned diagnostic and/or PCI films should only be transmitted upon the request of the CCC, Angio Core Lab or the Clincal Events Committee (CEC). The CEC may also request other documents including discharge summary, ECG, and/or cardiac enzymes.