

Netherlands ISCHEMIA Update



INTERNATIONAL STUDY OF COMPARATIVE HEALTH EFFECTIVENESS WITH MEDICAL AND INVASIVE APPROACHES

NYU Cardiovascular Clinical Research Center

Netherlands November 2015

News in the Netherlands



Radboud University Medical Center Dr. Suryapranata and Study Team randomized the first Dutch ISCHEMIA participant in July 2015 putting the Netherlands on the board.



Cardio Research Hartcentrum OLVG

Dr. Riezebos and Study Team randomized the first ISCHEMIA-CKD participant in September 2015 putting the Netherlands on the board for ISCHEMIA-CKD.

Welcome Isala Klinieken Weezenlanden!

Dr. Jorik Timmer will be leading ISCHEMIA's 3rd activated site in the country. We thank the team from Isala Klinieken Weezenlanden for their help in getting their site ready for enrollment!

ISCHEMIA Trial Update

ISCHEMIA has surpassed BARI2D and COUR-

AGE in the total number of participants.

(as of November 19, 2015) Enrollments Worldwide: 4058 Netherlands: 5 Randomizations Worldwide: 2404 Netherlands: 1

Strategies to Improve Enrollment

- ◆ Screen stress labs (NUC, ECHO, CMR, ETT) for positive tests
- Ask imaging physicians to notify the study team when there is an eligible patient; provide imaging physicians with study criteria for their reference
- Host local meetings with imaging physicians, interventionalists, and primary care physicians to publicize the study (CCC can provide slides)
- Engage local thought leaders to raise awareness of the study
- Meet with colleagues who are able to refer patients to ensure they understand the protocol and address any questions or concerns
- Send letters to referring physicians (CCC can provide templates)

Transmitting images and other documents to core labs.

- Stress images (NUC, ECHO, CMR) and CCTA images need to be uploaded via BioClinica WebSend. Please also include completed technical worksheets at the time of upload or upload them via BioClinica WebView (www.websend.bioclinica.com).
- ETTs need to be sent to the CCC via SendSafe. Please attach ETT tracings (showing rest, peak exercise, and recovery) and the completed technical worksheet to <u>ischemia@nyumc.org</u>
- If you experience any issues with BioClinica WebSend or Web-View, please contact the BioClinica Helpdesk for assistance at HelpDeskMailbox@bioclinica.com.

The ISCHEMIA Clinical Coordinating Center Telephone: 001-212-263-4225 Fax: 001-646-754-9621 Mailbox: ischemia@nyumc.org Website: www.ischemiatrial.org Netherlands Clinical Helpline: 0800-3949065

IMPORTANT!

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

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

ISCHEMIA-CKD Trial Update Enrollments: 156 Randomizations: 152 Website: www.ischemiackd.org



Website: <u>www.ischemiackd.org</u> Our thanks to Dr. Riezebos' team at OLVG for their contribution!