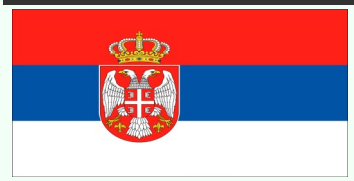
Serbia ISCHEMIA Update

INTERNATIONAL STUDY OF COMPARATIVE HEALTH EFFECTIVENESS WITH MEDICAL AND INVASIVE APPROACHES

NYU Cardiovascular Clinical Research Center — November 2015



TRIAL UPDATE

As of November 19th, 2015

Total Enrolled: 4058

Serbia: 64

Total Randomized : 2404

Serbia: 24

ISCHEMIA-CKD Trial Update

Enrollments: 158

Randomizations: 153

Website: www.ischemiackd.org

Our thanks to Dr. Beleslin & team at Clinical Center of Serbia for randomizing 4 in ISCHEMIA-CKD!

Site Name and Study Staff	Enrolled	Randomized
Institute of Cardiovascular Diseases, Sremska Kamenica Dr. Nada Cemerlic Adjic, Dr. Lazar Velicki, Dr. Ljiljana Pupic	16	8
Cardiology Clinic at Clinical Center of Serbia Dr. Branko Beleslin, Dr. Vojislav Giga	11	6
University Clinical Hospital Zvezdara Dr. Milica Dekleva, Dr. Miroslav Martinovic, Dr. Gordana Stevanovic	7	5
University Hospital Center Bezanijska Kosa Dr. Sasa Hinic, Dr. Gordana Antic, Dr. Marija Zdravkovic	16	3
Clinical Center of Serbia Dr. Petar Seferovic, Dr. Milan Dobric	3	1
Clinical Center Nis Dr. Svetlana Apostolovic, Dr. Dragana Stanojevic, Dr. Sonja Salinger-Martinovic	4	1
Cardiovascular Institute Dedinje, Belgrade, Serbia Dr. Ljiljana Jovovic. Dr. Dragana Kosevic	7	0

Reminders! **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.**

Non-protocol assigned diagnostic and/or PCI films should only be transmitted upon the request of the CCC, Angio Core Lab or Clinical Events Committee (CEC). The CEC may also request other documents including discharge summary, ECG, and/or cardiac enzymes.
OMT reports will soon be sent each month. Please review the report to ensure your participants are meeting their goals.

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Strategies to Improve Enrollment

- Screen stress labs (NUC, ECHO, CMR, ETT) everyday 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)

We are excited to announce the launch of the ISCHEMIA, ISCHEMIA-CKD, and CIAO-ISCHEMIA Facebook page! It will feature trial milestones, updates, study teams, exciting new findings in the research community, and much more! Share in our excitement by visiting us at https://www.facebook.com/ISCHEMIA.Trial and sharing the page with your colleagues. We hope you "like" it, and welcome your suggestions for topics to feature on the page.

Like us on Facebook

At which visit?

Some data items are easily missed! Below is a list of commonly missed data items and when they should be collected.

Blood Pressure- Every Visit
Heart Rate-Every Visit
Weight-Every Visit
Medications– Assess at every visit
Hospitalizations– Assess at every visit
Lipid Panel/HbA1c*- Every visit except 1.5M and CCTA visits
Creatinine-Every 12 months after RAND visit (For CKD ONLY)

You may also contact the participants' GP or check other sources that may have this information. For a full breakdown of required study related activities, be sure to check the *Schedule of Assessments* (available on page 42 in Version 2.0 of the protocol)!

*Include lipid panel (preferably fasting), HbA1c (diabetic patients only), and liver transaminases (if indicated). Full blood count and chemistry panel (at rand only unless indicated). If LDL cholesterol was at goal on the most recent lipid panel, and no change in statin or other lipid therapy has occurred, it is not necessary to repeat a lipid panel until the next scheduled 6-month visit.

The ISCHEMIA Clinical Coordinating Center

Telephone: 001-212-263-4225
Fax: 001-646-754-9621
Mailbox: ischemia@nyumc.org
Website: www.ischemiatrial.org
Serbia Clinical Helpline: 800-190-047

FOCUS Clinical Research Center

ISCHEMIA Managing Director: Nevena Garcevic
nevena.garcevic@focus-belgrade.com