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ISCHEMIA Clinical Coordinating Center

NIH National Heart, Lung, and Blood Institute

International Study of Comparative Health Effectiveness with Medical and Invasive Approaches

NYU Cardiovascular Clinical Research Center | March 2018 Newsletter

Data Clean-Up Goals & Deadlines

As we continue to focus on data cleanliness, please follow these visit-specific goals to complete all data entry by the deadlines below:

Visit	ENROLLMENT	RANDOMIZATION	MONTH 1.5	MONTH 3
	February	March	April	July
Deadlines for 100% COMPLETION	PAST DUE 16	PAST DUE 16	30 **Upcoming Deadline** PRIORITIZE	13

All InForm items, forms, and open queries for all participants should be completely resolved by the deadlines above. Contact your CCC regional team if you have any questions about data entry. **Data Quality Awards** will be announced soon and the following factors will be considered: number of data issues resolved within 14 days, number of randomizations, and randomization rate. Click here for our Study Visit Checklists and CRF Guidelines.

Biorepository Reminder

Enrollment is now over! If you have not yet, please contact ischemiabiorepository@nyumc.org if you have any remaining biorepository samples at your site. Feel free to reach out with any questions!

Device Donations Ending

Device donations (*including stent and FFR wire donations*) will cease for the main trial and CKD after **June 30th, 2018**. Any pending INV procedures should be scheduled as soon as possible. If you are having difficulty, please contact the CCC so we can help facilitate any pending replacements.

Meetings & Events

Please click here for the full list of webinars in 2018. (username: ischemia | password: member)

New Study Coordinator Training Webinars
April 19, 2018
10:00 – 11:30am & 5:00 – 6:30pm EST

InForm EDC Webinar
April 4, 2018
11:00am – 12:00pm EST

Study Update for Principal Investigators
April 10, 2018
10:00 – 11:00 am EST

The ISCHEMIA Clinical Coordinating Center

Telephone: 212-263-4225 | **Fax:** 646-754-9621 | **Email:** ischemia@nyumc.org
Website: www.ischemiatrial.org | **Website Login → username:** ischemia | **password:** member
US/Canada Helpline: +1-833-251-7491 (Physician on call for urgent matters - See Manual of Operations for Country Specifics)

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Medication Provision Program

Thanks to the companies listed below, the drugs listed below are available at no cost in certain countries. Please contact ISCHEMIA@nyumc.org for more information about how to order these drugs.

Country	Drugs	Company
Argentina	Vytorin and Zetia	Merck
Brazil	Crestor and Brilinta	AstraZeneca
	Vytorin and Zetia	Merck
Canada	Crestor and Brilinta	AstraZeneca
	Nitrolingual Spray	Arbor/Pohl Boskamp
	Repatha	AMGEN
Mexico	Crestor and Brilinta	AstraZeneca
Russia	Ezetrol	Merck
	Liprimar	Pfizer
Singapore	Crestor and Brilinta	AstraZeneca
USA	Crestor and Brilinta	AstraZeneca
	Edarbi and Edarbyclor	Arbor
	GoNitro	Espero Pharma
	Repatha	AMGEN
	Vytorin and Zetia	Merck

ISCHEMIA Publications Corner

This month the ISCHEMIA Design Paper was submitted to American Heart Journal.

More manuscripts are on the way!

# ABSTRACTS PUBLISHED	6 Abstracts
# MANUSCRIPTS SUBMITTED	1 Manuscript
# MANUSCRIPTS IN VARIOUS STAGES OF PREPARATION	22 Manuscripts
# SITE INVESTIGATOR AUTHORS TO BE INVITED TO WRITING GROUPS	~220 Investigators

It's not too late to fill in a survey to participate as an author! Click here to do so.
ANY QUESTIONS?
Contact us at ISCHEMIA@nyumc.org

CIAO ISCHEMIA Tips for Follow Up Visits

Use your site's IRB/EC approved **FULL Baseline EQoL Questionnaire** at all CIAO visits.

Set aside time to administer the EQoL in person, when possible. Do not send the participant away with the questionnaire for completion, especially at Month 12 when it may be more difficult to get it back.

Use the Month 6 visit as an opportunity to schedule the one year repeat stress echo in advance.

Click HERE for the CIAO-ISCHEMIA Visit Scheduler to help you calculate your CIAO follow-up visit windows.

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Improving Protocol Adherence for INV Participants

CATHETERIZATION:

- Schedule catheterization and revascularization (PCI or CABG) as soon as possible.
- Maintain communication with the participant between the time of randomization and the scheduled catheterization.
- Suggest consent for diagnostic catheterization alone, without PCI and/or CABG. Discussions regarding PCI and CABG are often best done in the context of specific anatomic findings at cardiac catheterization.
- If a participant refuses catheterization, engage the personal physician to help. Catheterization and revascularization performed late is much better than never performed!
- Contact the CCC for ALL refusals as soon as you become aware of them. **Randomized participants who refuse their assigned strategy or any other aspect of the protocol should not be withdrawn from the study!** These participants should continue to attend all study visits.
- If considered appropriate by the PI, you may share and review coronary study-CCTA images with the participant which may help them reconsider catheterization and revascularization.

REVASCULARIZATION:

- Discuss revascularization options after specific anatomic findings from diagnostic catheterization are known.
- If a participant refuses to undergo CABG, assess suitability for PCI and, if appropriate, attempt as complete a revascularization as possible.
- At each subsequent visit, ask the participants if they have changed their mind about having the revascularization procedures performed.
- Reassure the participant that your center is highly skilled at PCI and CABG; only highly skilled centers with an excellent track record are selected for trial participation!

Participant Retention

Now more than ever, keeping participants in the trial is of utmost importance!
The end of this phase of follow-up is planned for June 30, 2019 after which we will transition to long term follow-up.

In order to practice good participant retention:

- Build your participants' trust in their medical team using efficiency and teamwork.
- Establish a good relationship between the participant and medical team.
- Maintain an up-to-date contact list for each participant.
- Identify participants at risk for non-adherence/withdrawal and devise a retention strategy.
- If returning to the clinic for follow up visits is problematic, consider reimbursement for transportation if it can help mitigate the issue. Contact the CCC for details.