The Canadian Cardiac Chronicle

Volume 19, No. 3 Fall 2015

"Life is like riding a bicycle. To keep your balance, you must keep moving."

— Albert Einstein

Autumn means that we have moved forward, nearly completing another year. As a clinical and research community, it means 2 important gatherings are upon us – the American Heart Association and the Canadian Cardiovascular Congress. These meetings have long served as important educational and scientific milestones for our national and international collaborations. This year, we are looking forward to seeing our trainees and colleagues present their work at both of these conferences: those details are noted elsewhere in the Chronicle. Many of these posters or oral presentations would not have been possible without the collaborative efforts by each site, diligently collecting and entering data in each research project. Our patient partners in this effort rarely get to see this impact that stems from their volunteer spirit. This volunteerism provides extensive data ranging from vital signs, blood for biomarkers and imaging data, along with quality of life and health economic data. To this data, add a dose of mentorship and equal parts biostatistical support and co-investigator insight, and after appropriate shaking and stirring a trainee can be energized and a new line of investigation emerges or an expanded understanding of the 'primary' manuscript unfold. It is by these collective efforts that we train and expand our pool of clinician scientists in Canada, necessary for maintaining and advancing our research excellence. Yet exposure to this process for those that choose clinical practice is also key to being able to critically appraise the literature and engage in future collaborative research.

Education and training comes in many forms and we encourage our investigators, research personnel, and trainees to learn from each other. This interaction helps simplify some trials (e.g. shortening case report forms) and increase complexity inherent with other lines of inquiry (e.g. collecting serial blood tests in short periods of time). Additionally, trials that seek to be explanatory (e.g. does this intervention cause a specific benefit in highly controlled environments; e.g. AEGIS, BLAST-AHF) require different design and focus that those that seek to be pragmatic (e.g. does this intervention work in usual conditions; e.g. SODIUM-HF, PROACT-4). The design of the research question and subsequent trials takes collective effort to ensure we can deliver meaningful results. No idea, thought, practical consideration, concern, or local insight should be ignored in this scientific process.

In This Issue:

We encourage our sites to join us in Toronto as we host a CVC Reception on Sunday, October 25, 2015 at 6:00pm (details enclosed) and attend one of the many scientific sessions that your work helped to bring to fruition. We also provide our traditional educational offerings at CCC that cover the spectrum of disease states, under the Beyond2000 umbrella http://beyond2000.org. We have a panel of national and international experts in a dynamic program on Sunday morning (Acute Coronary Syndromes, Rm 718AB, 0700-0900) and Monday morning (Heart Failure and Atrial Fibrillation, Rm 718AB, 0700-0900).

With autumn comes an expectation of winter, and as a reminder to all of us for when the temperature has dropped, spring will cycle through: much like the cycle of clinical research and new information.

Justin Ezekowitz

LEVO-CTS

There was a terrific turnout from CVC sites and it was wonderful to meet so many of you at the Investigator's Meeting that was held in Chicago on June 2-3, 2015, where training on the protocol and the eCRF took place. (For the few sites who did not attend, protocol and eCRF training will occur during your SIV.) The take-home message from the investigator meeting was to emphasize just how important the CKMBs and ECGs are to the success of the trial, and that these tests need to be collected for every patient in the trial at all protocol-required timepoints.

As of September 1, 2015, over 165 patients (at more than 40 sites) have been randomized into this study that aims to evaluate the efficacy and safety of Levosimendan compared with placebo in reducing the composite of all-cause death or use of mechanical assist; OR the composite of all-cause death, perioperative MI, need for dialysis, or use of mechanical assist, in subjects with reduced LVEF undergoing cardiac surgery on CPB.

In Canada, as of August 31, 2015, four sites have been activated for enrollment:

1. Dr. Mazer, Charmagne Crescini & Sanjay Yagnik (St. Michael's Hospital, Toronto)

2. Dr. Arora & Wendy Janz (St. Boniface Hospital, Winnipeg)

3. Dr. Kalavrouziotis & Hugo Tremblay (Hopital Laval, IUCPQ, Quebec)

4. Dr. Whitlock & Thais Creary (Hamilton Health Sciences, Hamilton)

Dr. Mazer's site was the first to be activated in Canada in late July, and the team randomized their first patient less than a week later in early August (making them the first site to enroll a patient in Canada). They enrolled so quickly that they set a new record for the fastest randomization following site activation for the trial! Dr. Mazer's team has set the bar high for this study in Canada and the US!

We look forward to seeing the other activated sites randomize their first patients soon, and meet or exceed the enrollment target of 1 patient per month. Meanwhile, we continue to work through start-up with the six remaining CVC sites, with the goal to have them activated and ready to screen/enroll patients by the end of September.

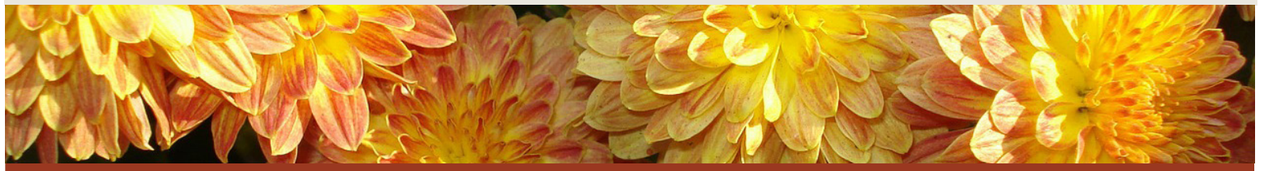
Stay tuned to see if Dr. Mazer's site continues their reign as the "fastest site to randomize a patient", or whether another Canadian site earns that title!

If you have any questions about this trial, please contact Clinical Trial Project Lead, Jodi Parrotta at 1-800-707-9098 ext. 3 or by email at jodi.parrotta@ualberta.

Sponsored by Tenax Therapeutics, Inc., LEVO-CTS is a Double Blind, Randomized, Placebo-Controlled Study of Levosimendan in Patients with Left Ventricular Systolic Dysfunction Undergoing Cardiac Surgery Requiring Cardiopulmonary Bypass.

LEVO CTS
levosimendan in cardio thoracic surgery

ClinicalTrials.gov Identifier: NCT02025621



PROACT

Exciting News!! The PROACT Study has been selected as a Late Breaking Clinical Trial to be presented at the American Heart Association meetings in Orlando, Florida on Tuesday, November 10th from 10:45 to 12:10 in Hall D. We hope to see you there.

This is a great accomplishment and it could not have possible without the collaborative effort of Edmonton Emergency Services and the Emergency Department Staff at the 5 major hospitals in Edmonton.

This very important milestone has been reached through the support of University Hospital Foundation, Alberta Health Services, Heart and Stroke Foundation and Alere Inc.

For further information regarding this trial, please contact Paula Priest at 1-800-707-9098 ext. 9 or paula.priest@ualberta.ca.

Providing **R**apid **O**ut of Hospital **A**cute **C**ardiovascular **T**reatment

PROACT

An Edmonton-region local initiative sponsored by the University Hospital Foundation and the Mazankowski Alberta Heart Institute. Additional support for point of care meters provided by Alere Inc.

ClinicalTrials.gov Identifier: NCT01634425

ODYSSEY OUTCOMES

The ODYSSEY Outcomes trial is quickly approaching the recruitment finish line! Thanks to a fantastic job from all 38 of our active sites, Canada has now contributed over 300 patients. Globally we have over 16,000 patients randomized, and as last communicated, we anticipate that we will hit the 18,000 patient mark sometime in November. We thank you all for your continued support of this important trial! We would like to recognize Canada's top recruiting sites (based on randomizations):

PI Manohara Senaratne – SC Himani Ferdinandis – 23 Randomized

PI James Stone – SC Meagan Heard – 21 Randomized

PI Stephen Pearce – SC Lynn Breakwell – 17 Randomized

PI Danielle Dion – SC Andrée Morissette – 17 Randomized

PI Gilbert Gosselin – SC Margaux David – 15 Randomized

As you have all seen over the summer months, communications regarding end of recruitment are being sent out by the sponsor via e-blasts and global newsletters. Please continue to pay special attention to these communications so that you are well informed of the most up-to-date timelines. A reminder that as we near the end of recruitment, we need all of our sites to continue to update Almac IVRS within 24 hours of a decision to screen fail a patient. Also, please remember to schedule randomization visits for patients who do qualify for the study, as soon as possible.

A new Investigator Brochure – edition 8 Amendment 1 – was recently posted to the MedPoint portal. Please be sure to review the e-mail communication sent out to all sites regarding the updated IB and required actions on your part. We look forward to the coming Amendment and updated informed consent forms in the very near future.

Canada has done an excellent job to date on data cleaning – thank you for all of your hard work! Please ensure that you continue to keep on top of your data queries, making sure that they are responded to within 5 days. We would also like to encourage you to pay special attention to the "data cleaning" emails that we send out, as these also list out all of the missing pages that need to be completed for your site. Special attention also needs to be given to any patients that are part of the 'cleaning cohorts'. These cohort patients need to be 100% clear of queries and missing pages, and this status needs to be maintained as new visits are completed.

We look forward to speaking with all of you on our next Canadian Update WebEx call on October 1st! Please be sure to let us know if you have any questions or topics you would like discussed on the next call.

For further information regarding this trial, please contact Clinical Trials Project Lead, Amanda Carapellucci at 1-800-707-9098 ext. 2 or by email at amanda.carapellucci@ualberta.ca or Paula Priest ext. 9 or paula.priest@ualberta.ca.

Sponsored by Sanofi-aventis Recherche & Développement this is a randomized, double-blind, placebo-controlled, parallel-group study to evaluate the effect of Alirocumab on the occurrence of cardiovascular events in patients who have recently experienced an Acute Coronary Syndrome.

ODYSSEY OUTCOMES

ClinicalTrials.gov Identifier: NCT01663402

GUIDE-IT

The GUIDE-IT trial currently has 660 subjects randomized (Canada: 94) as of 3-Sept-2015. We have exceeded the enrollment threshold, set by the NIH, of 620 subjects randomized by the end of August 2015. Thank you to all Investigators and Coordinators for contributing to this success – August was another solid month of enrollment for Canada with 5 subjects randomized.

• Congratulations to Dr. Toma and Cynthia Van Hoof in Vancouver on randomizing 3 subjects in August!

We hope to see strong enrollment trends continue in September as our goal is to have 100 subjects randomized by the Investigators Meeting (September 29, 2015). The upcoming IM will be held in Washington, DC and will focus on the critical issue of adherence in subjects randomized to the biomarker-guided arm. At least 1 person from each Canadian site has registered to attend; any late registration requests should be directed to Melisa.

Thank you to all Study Coordinators for resolving queries and ensuring your data is up-to-date for the DSMB meeting. We receive consistent feedback that Canada is doing well with query resolution and data entry. We encourage sites to enter visit data within 5 days of the visit. The monitors suggest setting aside time on Fridays (for example) to review Inform for queries (especially CEC queries) and stay on top of data entry.

Welcome to Susan Bonar, CRA, who will be monitoring the GUIDE-IT sites in Western Canada over the coming months. Halina Nawrocki, Lead CRA, will continue to monitor sites in Ontario and provide additional monitoring assistance as needed.

For further information, please contact Clinical Trial Project Lead Melisa Spaling at mspaling@ualberta.ca or direct: 1-780-492-8476.

In collaboration with DCRI (Duke Clinical Research Institute) and Roche, GUIDE-IT is a prospective, randomized 1:1, multi-centre clinical trial **GUID**ing **E**vidence Based Therapy Using Biomarker **I**ntensified **T**reatment in Heart Failure.

GUIDE-IT

ClinicalTrials.gov Identifier: NCT01685840

TECOS

TECOS is moving swiftly towards final close-out as we continue to receive REB close out letters and the final documents from sites. The primary results were presented at the American Diabetes Association 75th Scientific Sessions in Boston this June and were promising, concluding that among patients with type 2 diabetes and established cardiovascular disease, adding sitagliptin to usual care did not appear to increase the risk of major adverse cardiovascular events, hospitalization for heart failure, or other adverse events.

CVC is looking forward to welcoming our Canadian sites to a special dinner meeting during the Canadian Cardiovascular Congress this October in Toronto, where the primary results as well as some additional TECOS data presented at the European Society of Cardiology this September will be discussed.

For further information, please contact Clinical Trial Project Lead, Lyndsey Garritty at 1-800-707-9098, ext. 8 or by email at lyndsey.garritty@ualberta.ca.

Sponsored by Merck & Co. Inc., TECOS is a Randomized, Placebo Controlled Clinical **T**rial to **E**valuate **C**ardiovascular **O**utcomes after Treatment with **S**itagliptin in Patients with Type 2 Diabetes Mellitus and Inadequate Glycemic Control.

TRIAL EVALUATING CARDIOVASCULAR TECOS OUTCOMES WITH SITAGLIPTIN

ClinicalTrials.gov Identifier: NCT00790205

SODIUM-HF

The SODIUM-HF trial currently has 122 subjects enrolled (3-Sept-2015) at 15 active sites. The summer was a relatively strong period of enrollment, with 16 subjects randomized in July – a new trial record! We look forward to seeing similar enrollment trends in the fall. Please note there is a new enrollment challenge for all sites to enroll 2 subjects per month in September, October and November!

Congratulations to:

- Dr. Ezekowitz, Quentin Kushnerik and Elizabeth Woo on randomizing the trial's 100th subject early in July!

- Dr. Escobedo and Jubia Valezquez on randomizing the trial's first three subjects in Mexico!

We look forward to connecting with site personnel during the upcoming teleconference:

- Dietitian Working Group Teleconference: Thursday, November 19, 1 – 2 PM Mountain / 3 – 4 Eastern

Reminders:

• 3-day food records should be submitted within 3 business days of the study visit to sodium-corelab@ualberta.ca

• Patients should be randomized on the day of their baseline visit. This eliminates a number of potential problems that occur if a patient is randomized but does not show up for baseline.

• Patients randomized to the Usual Care arm have a Dietitian visit and complete a Food Record three times: Baseline, 6 months and 12 months. These patients do not see the Dietitian or complete the Food Record at the 3 and 9 month visits. (If the patient brings a completed Food Record to the 3 or 9 month visit, you should not review it with the patient. Please forward it to the core lab.)

• Patients randomized to the Low-Sodium arm have a Dietitian visit and complete a Food Record five times: Baseline, 3 months, 6 months, 9 months, and 12 months.

If you are interested in further information about SODIUM-HF, please contact Clinical Trial Project Lead, Melisa Spaling at 780-492-8476 or via email at mspaling@ualberta.ca.

Funded by the Canadian Institute of Health Research (CIHR), SODIUM-HF is a multicenter, randomized, open-label **S**tudy **O**f **DI**etary Intervention **U**nder 100 **M**MOL in **H**eart **F**ailure.

SODIUM-HF

ClinicalTrials.gov Identifier: NCT02012179

The Canadian Cardiac Chronicle - Volume 19

EXSCEL

CVC would like to extend our appreciation to each of our Canadian sites for their continued efforts with retention. With only one lost to follow up patient to date in Canada we are very pleased with the efforts from our sites.

As a reminder, we want to really focus and encourage all sites to work at keeping patients on study drug for the remainder of the study. To assist in this effort a new 'TrialNetworks' tool will soon be launched to help sites track patients who have discontinued study medication. The tool will also provide some useful talking points and educational materials to assist with bringing patients, who have discontinued study medication, back on (where appropriate). In the meantime, it is vital you continue to contact the Hotline physician regarding any patients who are considering or have discontinued study drug so that we may explore all options for keeping them on their medication.

The next DSMB meeting has been scheduled for November 2015. This means that we need to have all data entered and clean by September 30th, 2015. Please prioritize your CEC queries and late visits but aim to clean up all outstanding items as soon as possible. We are always eager to assist you with any questions or issues you may have so please don't hesitate to contact your Project Lead for help.

The 2015 EXSCEL North America Rejuvenation Meeting is scheduled for October 15th -16th in Alexandria, VA. Invitations have gone out and we look forward to seeing you there! Please stay tuned for the forthcoming agenda.

For further information about this trial, please contact Clinical Trial Project Lead, Karin Kushniruk at 1-800-707-9098, ext. 1 or by email at kushniru@ualberta.ca.

Exenatide **S**tudy of **C**ardiovascular **E**vent **L**owering

EXSCEL

Sponsored by AstraZeneca, this trial is a pragmatic, long term, placebo-controlled, double-blinded trial which seeks to characterize the effects of exenatide once weekly on cardiovascular(CV) -related outcomes in patients with type 2 diabetes when added to the current usual care for glycemic control in a standard care setting.

ClinicalTrials.gov Identifier: NCT01144338

AEGIS-I

Global enrollment has been on the fast track the last few months and Main Study enrollment is now over 900 patients! The recruitment phase of the study will end at 1200 patients. Recruitment is competitive and with this target number getting closer we are very focused on increasing our Canadian enrollment numbers to ensure that our sites have every opportunity to contribute to this important study. We know that everyone is hard at work screening so we are optimistic that with your dedication Canada can increase their overall recruitment over the next couple months!

Congratulations to all of our enrolling sites!

Dr. Bruce Sussex & Jill Cole – St. John's, NFLD – 4 patients

Dr. Samer Mansour & Catherine Bouchard-Pilote – CHUM, Montreal, QC – 2 patients

Dr. David Cleveland & Susan Valley – Penticton Regional Hospital, Penticton, BC – 1 patient

Dr. PoKee Cheung & Linda Kvill – Royal Alexandra Hospital, Edmonton, AB – 1 patient

Dr. Minh Vo & Camille Meub – St. Boniface, Winnipeg, MB – 1 patient

Dr. Robert Welsh & Norma Hogg – University of Alberta Hospital, Edmonton, AB – 1 patient

A few reminders:

Data entry is required within 2 business days of each visit and queries are expected to be reviewed and answered quickly. Thank you to our sites for continuing to enter data in a timely and efficient manner.

Please ensure that all regulatory documents and REB submissions and approvals pertaining to Protocol Amendment #3 have been sent to CVC.

For further information, please contact Blinded Clinical Trial Project Lead, Lyndsey Garritty at 1-800-707-9098, ext 8 or via email at lyndsey.garritty@ualberta.ca or Unblinded Clinical Trial Project Lead Tracy Temple @ 1-800-707-9098 ext. 5 or via email at tracy.temple@ualberta.ca.

Sponsored by CSL Behring LLC, this study is a Phase 2b, multi-center, randomized,placebo-controlled, dose-ranging study to investigate the safety and tolerability of multiple dose administration of CSL112 in subjects with acute myocardial infarction.

AEGIS-I

ClinicalTrials.gov Identifier: NCT02108262

BLAST-AHF

Congratulations to Dr. Haddad, Ann Baker and Laura Menchini and their team in Ottawa, ON on randomizing Canada's first subject in the BLAST-AHF trial! We look forward to additional enrollments at their site as well as our other participating Canadian sites.

There are over 370 subjects enrolled in the trial with over 60 active sites – well on the way to achieving the enrollment target of 620 subjects! With the push to complete enrollment near the end of this year we encourage our sites to keep actively screening. CVC will continue to keep you up-to-date on study timelines.

Thank you to all study sites for your efficient return of expired study drug; all sites have been re-supplied with new study drug supplies (expiry date is either January 2016 or March 2016). As a reminder, study drug is auto resupplied via IVRS based on rate of enrollment at your site.

Reminders:

o Please remember to enter the study data within 5 days of the study visit. The monitor will be on site within 1 week of the Day 5 study visit.

o Lab kits and supplies are not auto-resupplied. Please be sure to check the expiry dates as the various kits expire at different times. Log in to PPD INSITE to re-order any supplies you may need (note: please allow 2 weeks for delivery).

o As applicable, please check the expiry dates on your BNP kits and ensure adequate supplies are re-ordered well in advance.

If you have any questions about BLAST-HF, please contact Clinical Trial Project Lead, Melisa Spaling at 780-492-8476 or via email at mspaling@ualberta.ca.

Sponsored by Trevena Inc., BLAST-AHF is A Randomized, Double-Blind, Placebo-Controlled, Dose Ranging Study to Explore the Efficacy of TRV027 in Patients Hospitalized for Acute Decompensated Heart Failure.

ClinicalTrials.gov Identifier: NCT01966601

BLAST-AHF

GALILEO

GALILEO is a Phase III study that will enroll approximately 1500 patients and will look at the long-term benefit/risk profile of rivaroxaban, an oral Factor Xa inhibitor for the prevention of ischemic and thromboembolic events in patients post successful transcatheter aortic valve implantation (TAVI).

The Canadian VIGOUR Centre is pleased to be collaborating closely with the team from Icahn School of Medicine at Mount Sinai, New York, Bayer HealthCare AG and Cardialysis (Europe) on this exciting project. We are pleased to have CVC Faculty member, Dr. Robert Welsh with the University of Alberta Hospital, representing Canada on the Executive Committee and collaborating closely with the Lead Principal Investigators, Prof. Dr. George Dangas (Icahn School of Medicine at Mount Sinai, Mount Sinai Medical Center, New York, United States) and Prof. Dr. Stephan Windecker (Inselspital, University Hospital Bern, Switzerland).

Initial invitations have now been sent out and feasibility has started both in Canada and rest of world.

If you are a high volume TAVI site, with a research team in place and would be interested in hearing more about this study please contact Jodi Parrotta at jodi.parrotta@ualberta.ca or 1-800-707-9098 ext. 3.

Sponsored by Bayer Healthcare AG, GALILEO is a Global multi-center, open-label, randomized, event-driven, active-controlled study comparing a rivAroxaban-based anti-thrombotic strategy to an antipLatelet-based strategy after transcatheter aortIc vaLve rEplacement (TAVR) to Optimize clinical outcomes.

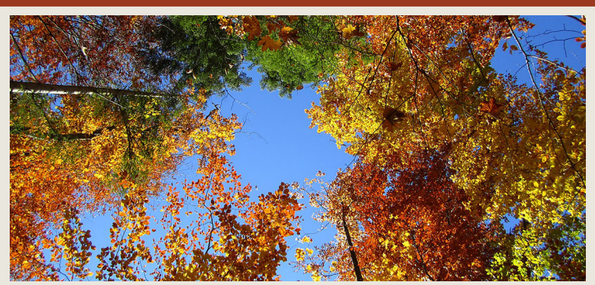
ClinicalTrials.gov Identifier: NCT02556203

GALILEO

Upcoming Trials

The Canadian VIGOUR Centre is partnering with the Duke Clinical Research Institute (DCRI), Stanford Center for Clinical Research and a global pharmaceutical company on an exciting Phase III study in patients with chronic heart failure. Importantly, this program is expected to enroll a broad range of patients with both reduced and preserved ejection fraction and hence be very inclusive.

Please stay tuned for more information coming your way this fall.



CVC News

Wendimagegn Ghidey Alemayehu (PhD) joined the CVC as a biostatistician as of July 20, 2015. He recently hails from the Erasmus Medical Center Cancer Institute in Rotterdam, the Netherlands and was granted a PhD in Biostatistics from the Katholieke Universiteite in Leuven, Belgium.

Kris Reay joined CVC as an Administrative Assistant in August 2015. She brings varied administrative experience from her work in the private and public sector. In her free time, Kris is an active community volunteer and enjoys spending time with her three children.

Karin Kushniruk, RN, PhD received her BScN at the University of Alberta and later earned her PhD in Prenatal and Perinatal Psychology. She has been a Registered Nurse since 2000 and worked in Neonatal Intensive Care throughout Canada and the United States. We anticipate her research experience at the University of California and Stanford University as a Research Nurse Coordinator will be valuable in the role of Project Lead for the EXSCEL trial. In her free time, Karin enjoys hiking, cooking, and spending time in the mountains with her husband.

Monitoring Tips

Does a deviation/violation from protocol matter? – The answer is YES.

A deviation/violation is a departure from the protocol/amendments and study requirements that has been approved by the REB. Upon discovering a protocol deviation/violation, the Principal Investigator is responsible for reporting this to the REB as per their reporting requirements and timelines. Documenting of the protocol deviation/violation is crucial as well as documenting a corrective action plan to ensure that the deviation/violation does not occur again. Examples of protocol deviations/violations:

• The subject did not sign an REB approved consent prior to any study related procedures.

• The site has not documented the consent process when recruiting a subject.

• Inclusion/exclusion criteria was not met.

• Prohibited medications were used.

• Protocol required tests were not performed.

• AE/SAE's are unreported.

• The subject missed study visits or the visits out of window.

• Study medication was not taken as per protocol.

For monitoring related questions please contact Halina Nawrocki at halina.nawrocki@rogers.com or Tracy Temple at ttemple@ualberta.ca.

Publications

Sepehrvand N, Zheng Y, Armstrong PW, Welsh R, Goodman SG, Tymchak W, Khadour F, Chan M, Weiss D, Ezekowitz JA. Alignment of site versus adjudication committee-based diagnosis with patient outcomes: Insights from the Providing Rapid Out of Hospital Acute Cardiovascular Treatment 3 trial.. Clin Trials. 2015 Aug 19. http://www.ncbi.nlm.nih.gov/pubmed/26289822

Kragholm K, Halim SA, Yang Q, Schulte PJ, Hochman JS, Melloni C, Mahaffey KW, Moliterno DJ, Harrington RA, White HD, Armstrong PW, Ohman EM, Van de Werf F, Tricoci P, Alexander JH, Giugliano RP, Newby LK. Sex-Stratified Trends in Enrollment, Patient Characteristics, Treatment, and Outcomes Among Non-ST-Segment Elevation Acute Coronary Syndrome Patients: Insights From Clinical Trials Over 17 Years. Circ Cardiovasc Qual Outcomes. 2015 Jul 7. http://www.ncbi.nlm.nih.gov/pubmed/26152683

Abualnaja S, Podder M, Hernandez AF, McMurray JJ, Starling RC, O'Connor CM, Califf RM, Armstrong PW, Ezekowitz JA. Acute Heart Failure and Atrial Fibrillation: Insights From the Acute Study of Clinical Effectiveness of Nesiritide in Decompensated Heart Failure (ASCEND-HF) Trial. J Am Heart Assoc. 2015 Aug 24;4(8). http://www.ncbi.nlm.nih.gov/pubmed/26304935

Shavadia J, Zheng Y, Dianati Maleki N, Huber K, Halvorsen S, Goldstein P, Gershlick AH, Wilcox R, Van de Werf F, Armstrong PW. Infarct Size, Shock, and Heart Failure: Does Reperfusion Strategy Matter in Early Presenting Patients With ST-Segment Elevation Myocardial Infarction? J Am Heart Assoc. 2015 Aug 24;4(8). http://www.ncbi.nlm.nih.gov/pubmed/26304934

Publications Continued

Khazanie P, Heizer GM, Hasselblad V, Armstrong PW, Califf RM, Ezekowitz J, Dickstein K, Levy WC, McMurray JJ, Metra M, Tang WH, Teerlink JR, Voors AA, O'Connor CM, Hernandez AF, Starling R. Predictors of clinical outcomes in acute decompensated heart failure: Acute Study of Clinical Effectiveness of Nesiritide in Decompensated Heart Failure outcome models. Am Heart J. 2015 Aug;170(2):290-297. http://www.ncbi.nlm.nih.gov/pubmed/26299226

Shavadia J, Norris CM, Graham MM, Verma S, Ali I, Bainey KR. Symptomatic graft failure and impact on clinical outcome after coronary artery bypass grafting surgery: Results from the Alberta Provincial Project for Outcome Assessment in Coronary Heart Disease registry. Am Heart J. 2015 Jun;169(6):833-840. http://www.ncbi.nlm.nih.gov/pubmed/26027621

Kelly JP, Mentz RJ, Hasselblad V, Ezekowitz JA, Armstrong PW, Zannad F, Felker GM, Califf RM, O'Connor CM, Hernandez AF. Worsening heart failure during hospitalization for acute heart failure: Insights from the Acute Study of Clinical Effectiveness of Nesiritide in Decompensated Heart Failure (ASCEND-HF). Am Heart J. 2015 Aug;170(2):298-305. http://www.ncbi.nlm.nih.gov/pubmed/26299227

Ezekowitz JA, Becher H, Belenkie I, Clark AM, Duff HJ, Friedrich MG, Haykowsky MJ, Howlett JG, Kassiri Z, Kaul P, Kim DH, Knudtson ML, Light PE, Lopaschuk GD, McAlister FA, Noga ML, Oudit GY, Paterson DI, Quan H, Schulz R, Thompson RB, Weeks SG, Anderson TJ, Dyck JR. The Alberta Heart Failure Etiology and Analysis Research Team (HEART) study. BMC Cardiovasc Disord. 2014 Jul 25;14:91. http://www.biomedcentral.com/1471-2261/14/91/prepub

Sharma A, Ezekowitz JA. Diabetes, impaired fasting glucose, and heart failure: it's not all about the sugar. Eur J Heart Fail. 2014 Nov;16(11):1153-6. http://www.ncbi.nlm.nih.gov/pubmed/25315254

Wang JY, Goodman SG, Saltzman I, Wong GC, Huynh T, Dery JP, Leiter LA, Bhatt DL, Welsh RC, Spencer FA, Fox KA, Yan AT; Global Registry of Acute Coronary Events (GRACE/GRACE-2); Canadian Registry of Acute Coronary Events (CANRACE) Investigators. Cardiovascular Risk Factors and In-Hospital Mortality in Acute Coronary Syndromes: Insights From the Canadian Global Registry of Acute Coronary Events. Can J Cardiol. 2015 Apr 17. http://www.ncbi.nlm.nih.gov/pubmed/26143140

Armstrong PW, Zheng Y, Westerhout CM, Rosell-Ortiz F, Sinnaeve P, Lambert Y, Lopes RD, Bluhmki E, Danays T, Van de Werf F; STREAM investigators. Reduced dose tenecteplase and outcomes in elderly ST-segment elevation myocardial infarction patients: Insights from the STrategic Reperfusion Early After Myocardial infarction trial. Am Heart J. 2015 Jun;169(6):890-898.e1 http://www.ncbi.nlm.nih.gov/pubmed/26027628

Mahaffey KW, Hager R, Wojdyla D, White HD, Armstrong PW, Alexander JH, Tricoci P, Lopes RD, Ohman EM, Roe MT, Harrington RA, Wallentin L. Meta-Analysis of Intracranial Hemorrhage in Acute Coronary Syndromes: Incidence, Predictors, and Clinical Outcomes. J Am Heart Assoc. 2015 Jun 18;4(6). http://www.ncbi.nlm.nih.gov/pubmed/26089177

Tarantini L, Barbati G, Cioffi G, McAlister FA, Ezekowitz JA, Mazzone C, Faganello G, Russo G, Grisolia EF, Di Lenarda A. Clinical implications of the CKD epidemiology collaboration (CKD-EPI) equation compared with the modification of diet in renal disease (MDRD) study equation for the estimation of renal dysfunction in patients with cardiovascular disease. Intern Emerg Med. 2015 Jun 30. http://www.ncbi.nlm.nih.gov/pubmed/26123617

Colin-Ramirez E, Castillo-Martinez L, Orea-Tejeda A, Zheng Y, Westerhout CM, Ezekowitz JA. Dietary fatty acids intake and mortality in patients with heart failure. Nutrition. 2014 Nov-Dec;30(11-12):1366-71. doi: 10.1016/j.nut.2014.04.006. Epub 2014 Apr 19. http://www.ncbi.nlm.nih.gov/pubmed/25280414

van Walraven C, McAlister FA, Bakal JA, Hawken S, Donzé J. External validation of the Hospital-patient One-year Mortality Risk (HOMR) model for predicting death within 1 year after hospital admission. CMAJ. 2015 Jun 8. pii: cmaj.150209. http://www.ncbi.nlm.nih.gov/pubmed/26054605

Tedjasaputra V, Bryan TL, van Diepen S, Moore LE, Bouwsema MM, Welsh RC, Petersen SR, Stickland MK. Dopamine receptor blockade improves pulmonary gas exchange but decreases exercise performance in healthy humans. J Physiol. 2015 May 8. http://www.ncbi.nlm.nih.gov/pubmed/25952760

Kholaif N, Zheng Y, Jagasia P, Himmelmann A, James SK, Steg PG, Storey RF, Westerhout CM, Armstrong PW. Baseline Q waves and time from symptom onset to ST-segment elevation myocardial infarction: Insights from PLATO on the influence of sex. Am J Med. 2015 Mar 25. http://www.ncbi.nlm.nih.gov/pubmed/25818495

Publication Information

This newsletter is published periodically as a service to Canadian investigational sites. The purpose is to provide information of interest to individuals involved in cardiovascular clinical trials managed by the Canadian VIGOUR Centre, University of Alberta in Edmonton, Alberta, Canada.

The VIGOUR (Virtual CoordInating Centre for Global COllaborative CardiovascUlar Research) group is an international academic group committed to advancing cardiovascular medicine and enhancing patient care worldwide. Its membership includes: the Canadian VIGOUR Centre (CVC), University of Alberta, Edmonton, Alberta, Canada; Green Lane Coordinating Centre, Auckland, New Zealand; National Health & Medical Research Council – Clinical Trials Centre, Sydney, Australia; Flinders Medical Centre, Bedford Park, Australia; Duke Clinical Research Institute (DCRI), Duke University, Durham, NC, USA; Leuven Coordinating Centre, University Hospital Gasthuisberg, Leuven, Belgium; ECLA, Rosario, Argentina, South America; TANGO, Buenos Aires, Argentina, South America; Uppsala Clinical Research Centre, Uppsala, Sweden

Address for Inquiries:
2-132 Li Ka Shing Centre for Health Research Innovation
University of Alberta, Edmonton, AB, Canada, T6G 2E1
Phone: 1-800-707-9098, Fax: (780) 492-0613
www.vigour.ualberta.ca

CVC gratefully acknowledges our sponsors and the funding support provided by:

Alere Inc.
AstraZeneca
Amylin Pharmaceuticals
CIHR
CSL Behring LLC
Heart & Stroke Foundation Can.
Merck & Co., Inc.
Bayer Health Care AG
National Institutes of Health/NHLBI
Roche Diagnostics Operations Inc.
Sanofi-Aventis Recherche & Développement
Tenax Therapeutics, Inc.
Trevena Inc.
Mazankowski Alberta Heart Institute
University Hospital Foundation