The CERC Chronicle

Issue No. 15 April 2019

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How an investigator initiated trial ended up as an FDA registration study

Three years ago, Pr C. Tamburino from Catania asked CERC to coordinate the SCOPE II study that he had initiated thanks to a grant from Symetis. This study was designed as a randomized trial of the Symetis neo™ valve versus Medtronic Corevalve, at a time when Pr S. Windecker was already conducting the SCOPE I randomized trial evaluating the same Symetis valve versus the Edwards Sapien, We gladly agreed to conduct Prof. Tamburino's trial as CERC was created with the express purpose of running trials likely to improve patient outcomes. Thereafter, during the recruitment period, Symetis was acquired by Boston Scientific, a company large enough to have a broader perspective. Boston Scientific decided to request FDA approval in order to access the US market using the SCOPE I and II data combined with an additional single arm North American trial. Even though the adaptation of the trial protocol to both RGPD and the new objective of the trials required complex discussions with all competent authorities and ethical committees, we succeeded in the end. Should all these trials have positive outcomes, we will be very proud at CERC to have helped patients benefit from faster access to new technologies. This uplifting story illustrates CERC's commitment to implementing the same rigorous quality control methods irrespective of whether trials stem from large or small companies or whether they are physician- or industry-initiated.

Marie-Claude Morice
CEO

MASTERDAPT


Marco Valgimigli


Pieter Smits

MASTER DAPT is an investigator-initiated, ECRI sponsored, open-label, multicenter, randomized controlled trial comparing an abbreviated versus a standard duration of antiplatelet therapy after bioresorbable polymer-coated Ultimaster sirolimus-eluting stent implantation in 4,300 HBR patients.

After a mandatory 30-day dual-antiplatelet therapy run-in phase, patients are randomized to a single antiplatelet regimen until study completion or up to 5 months in patients with clinically indicated oral anticoagulation (experimental 1-month DAPT group) or to DAPT continuation for at least 5 months in patients without or 2 in patients with concomitant indication for oral anticoagulation, followed by a single antiplatelet regimen (standard antiplatelet regimen). With a final sample size of 4,300 patients, this study is powered to assess the noninferiority of the abbreviated antiplatelet regimen with respect to the net adverse clinical and major adverse cardiac and cerebral events composite end points and, should non-inferiority be demonstrated, for the superiority of abbreviated as compared to standard antiplatelet therapy duration in terms of major or clinically relevant nonmajor bleeding. As of today, more than 3000 patients have been randomized, in more than 120 centers in 30 countries around the world. End of enrolment is scheduled for late 2019.

Bernard Chevalier
General Director

Philippe Urban
Director

Small bird for high hopes: The COLIBRI trial

CERC has started to implement the Colibri Heart Valve CE mark trial. This balloon-expandable THV was designed with an original leaflet geometry and material enabling a reduction in the mass of cusps with the potential benefit of a larger effective orifice area even in out-of-round shapes of the frame.

In combination with proprietary dry tissue preparation, this allows for a pre-mounted, pre-packaged, low profile (true 14F) delivery system. This company-sponsored trial will be conducted in ten centers in four European countries in order to enrol 60 patients with a 1-year primary endpoint and 5-year clinical and echographic follow-up.

Bernard Chevalier
General Director

ARC HBR

New HBR stent and DAPT trials


Mitch Krucoff

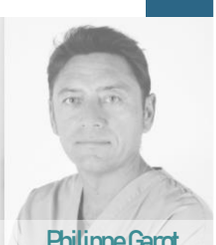
Following the successful completion and publication of the LEADERS FREE and SENIOR trials, CERC is proud to be associated with three other recently presented or on-going major clinical trials that focus on HBR patients:

LEADERS FREE II, presented last September at TCT by Mitch Krucoff (PI). This single arm 1200 patient IDE trial in the US and Europe has shown that the LEADERS FREE results of the BioFreedom stainless-steel DCS (Biosensors) with ultra short (1 month) DAPT are fully reproducible, both in the North American and the European environments.

In LEADERS FREE III, patients treated with one month DAPT only after PCI, is currently enrolling to evaluate a new thin-strut cobalt chrome DCS platform (Biosensors) and compare it to the historic BMS data from LEADERS FREE (PI's Franz Eberli and Philippe Garot).

Philippe Urban
Director


Franz Eberli


Philippe Garot

CERC quality department to fulfill worldwide regulations

Our Quality Department is the core of our Clinical Research Team which aims to provide high quality services for our trials all over the world.

We offer the Medical Device and Pharmaceutical Industries a scientific organization devoted to advanced and complex clinical development and we provide compliance with applicable regulations and Client expectations and requirements, We also continuously improve the effectiveness of our Quality Management Systems to support our clients and suppliers with the best trained staff in our field.
Since 2012 CERC has maintained the ISO 9001 standard certification and both CERC and CERC Asia are ISO 9001:2015 certified by TÜV Rheinland, the internationally recognized certification body.

CERC is regularly audited by Medical Device companies and ISO body, and no major findings have been identified over the last 3 years.

This is the guarantee that our sponsors trials are in good hands!

Hella Ajej & Isabelle Simoes
Quality team

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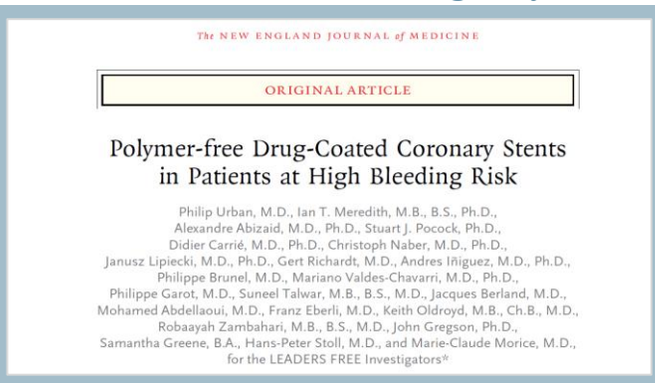
Publications of studies managed by CERC

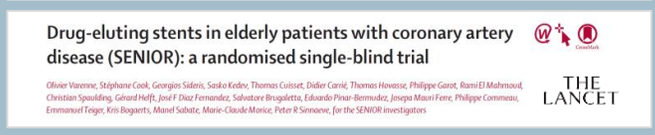


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk

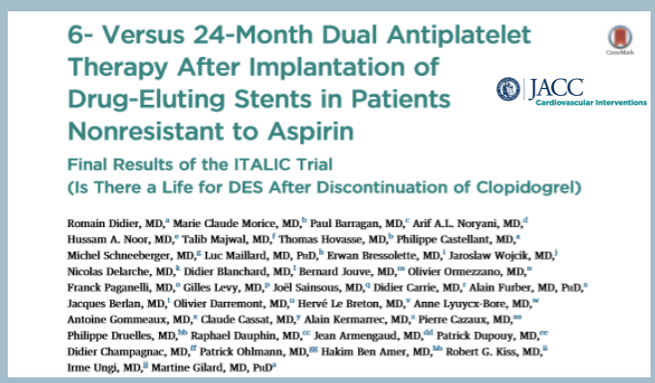
Philip Urban, M.D., Ian T. Meredith, M.B., B.S., Ph.D., Alexandre Abizaid, M.D., Ph.D., Stuart J. Pocock, Ph.D., Didier Carrié, M.D., Ph.D., Christoph Naber, M.D., Ph.D., Janusz Lipiecki, M.D., Ph.D., Gert Richardt, M.D., Andres Iñiguez, M.D., Ph.D., Philippe Brunel, M.D., Mariano Valdes-Chavarri, M.D., Ph.D., Philippe Garot, M.D., Suneel Talwar, M.B., B.S., M.D., Jacques Berland, M.D., Mohamed Abdellaoui, M.D., Franz Eberli, M.D., Keith Oldroyd, M.B., Ch.B., M.D., Robaayah Zambahari, M.B., B.S., M.D., John Gregson, Ph.D., Samantha Greene, B.A., Hans-Peter Stoll, M.D., and Marie-Claude Morice, M.D., for the LEADERS FREE Investigators*



Drug-eluting stents in elderly patients with coronary artery disease (SENIOR): a randomised single-blind trial

Olivier Varenne, Stéphane Cook, Georgios Sideris, Sasko Kedev, Thomas Cuisset, Didier Carrié, Thomas Hovasse, Philippe Garot, Rami El Mahmoud, Christian Spaulding, Gérard Helft, José F Diaz Fernandez, Salvatore Brugaletta, Eduardo Pinar-Bermudez, Josepa Mauri Ferre, Philippe Commeau, Emmanuel Teiger, Kris Bogaerts, Manel Sabate, Marie-Claude Morice, Peter R Sinnaeve, for the SENIOR investigators

THE LANCET

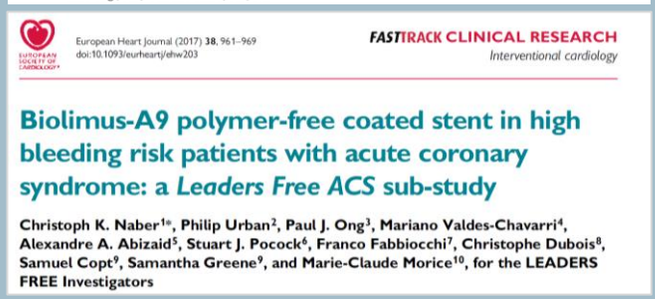


6- Versus 24-Month Dual Antiplatelet Therapy After Implantation of Drug-Eluting Stents in Patients Nonresistant to Aspirin

Final Results of the ITALIC Trial
(Is There a Life for DES After Discontinuation of Clopidogrel)

JACC Cardiovascular Interventions

Romain Didier, MD,[a] Marie Claude Morice, MD,[b] Paul Barragan, MD,[c] Arif A.L. Noryani, MD,[d] Hussam A. Noor, MD,[e] Talib Majwal, MD,[f] Thomas Hovasse, MD,[b] Philippe Castellant, MD,[a] Michel Schneeberger, MD,[g] Luc Maillard, MD, PhD,[h] Erwan Bressolette, MD,[i] Jarosław Wojcik, MD,[j] Nicolas Delarche, MD,[k] Didier Blanchard, MD,[l] Bernard Jouve, MD,[m] Olivier Ormezzano, MD,[n] Franck Paganelli, MD,[o] Gilles Levy, MD,[p] Joël Sainsous, MD,[q] Didier Carrie, MD,[r] Alain Furber, MD, PhD,[s] Jacques Berlan, MD,[t] Olivier Darremont, MD,[u] Hervé Le Breton, MD,[v] Anne Lyuycx-Bore, MD,[w] Antoine Gommeaux, MD,[x] Claude Cassat, MD,[y] Alain Kermarrec, MD,[z] Pierre Cazaux, MD,[aa] Philippe Druelles, MD,[bb] Raphael Dauphin, MD,[cc] Jean Armengaud, MD,[dd] Patrick Dupouy, MD,[ee] Didier Champagnac, MD,[ff] Patrick Ohlmann, MD,[gg] Hakim Ben Amer, MD,[hh] Robert G. Kiss, MD,[ii] Irme Ungi, MD,[jj] Martine Gilard, MD, PhD[kk]

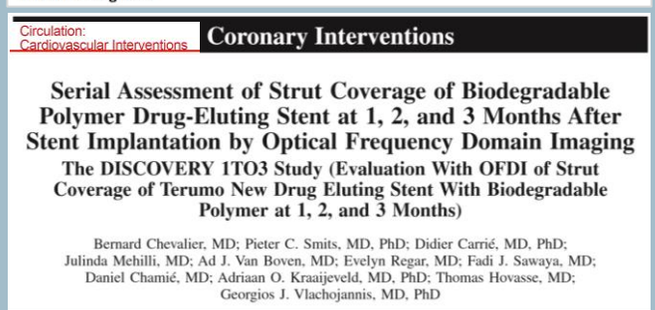


European Heart Journal (2017) 38, 961–969
doi:10.1093/eurheartj/ehw203

FASTTRACK CLINICAL RESEARCH
Interventional cardiology

Biolimus-A9 polymer-free coated stent in high bleeding risk patients with acute coronary syndrome: a *Leaders Free ACS* sub-study

Christoph K. Naber[1]*, Philip Urban[2], Paul J. Ong[3], Mariano Valdes-Chavarri[4], Alexandre A. Abizaid[5], Stuart J. Pocock[6], Franco Fabbiocchi[7], Christophe Dubois[8], Samuel Copt[9], Samantha Greene[9], and Marie-Claude Morice[10], for the LEADERS FREE Investigators



Circulation: Cardiovascular Interventions — Coronary Interventions

Serial Assessment of Strut Coverage of Biodegradable Polymer Drug-Eluting Stent at 1, 2, and 3 Months After Stent Implantation by Optical Frequency Domain Imaging

The DISCOVERY 1TO3 Study (Evaluation With OFDI of Strut Coverage of Terumo New Drug Eluting Stent With Biodegradable Polymer at 1, 2, and 3 Months)

Bernard Chevalier, MD; Pieter C. Smits, MD, PhD; Didier Carrié, MD, PhD; Julinda Mehilli, MD; Ad J. Van Boven, MD; Evelyn Regar, MD; Fadi J. Sawaya, MD; Daniel Chamié, MD; Adriaan O. Kraaijeveld, MD, PhD; Thomas Hovasse, MD; Georgios J. Vlachojannis, MD, PhD

Twelve-month results of a prospective, multicentre trial to assess the everolimus-eluting coronary stent system (PROMUS Element): the PLATINUM PLUS all-comers randomised trial

EuroIntervention

Jean Fajadet[1]*, MD; Franz-Josef Neumann[2], MD; David Hildick-Smith[3], MD; Sonia Petronio[4], MD; Azfar Zaman[5], MD; Mark Spence[6], MD; Jochen Wöhrle[7], MD; Simon Elhadad[8], MD; David Roberts[9], MD; Thomas Hovasse[10], MD; Mariano Valdés[11], MD; Sigmund Silber[12], MD; on behalf of the PLATINUM PLUS trial investigators

In press in JACC Cardiovascular Interventions

Transcatheter Aortic Valve Replacement for Failed Surgical Aortic Bioprostheses Using a Self-Expanding Device: One Year Results From the Prospective VIVA Post-Market Study

Didier Tchétché, MD[1]; Bernard Chevalier, MD[2]; David Holzhey, MD[3]; Axel Harnath, MD[4]; Ulrich Schäfer, MD[5]; Emmanuel Teiger, MD, PhD[6]; Thibaut Manigold, MD[7]; Thomas Modine, MD[8]; Geraud Souteyrand, MD[9]; Didier Champagnac, MD[10]; Jae K. Oh, MD[11]; Shuzhen Li, PhD[12]; Jean-Philippe Verhoye, MD[13]; Ran Kornowski, MD[14]; and on behalf of the VIVA Investigators*

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