



Randomized comparison of the clinical
Outcome of single versus
Multiple
Arterial grafts



**Weill
Cornell
Medicine**

ROMA Trial Newsletter

February 2018

Dear ROMA Study Teams,

The ROMA trial has opened at several sites, thank you all for all your hard work and dedication to this study. We look forward to the work ahead and our collaboration on this exciting trial!

Study Updates

We are pleased to announce that a Canadian Institute of Health Research (CIHR) grant has been awarded to ROMA!

As of February 7, 2018, the total enrollment is 43 subjects randomized.

As a reminder, please send your center's **Screening Log** on the 1st and 15th of each month to jctoit@med.cornell.edu.

Congratulations Dr. Ruttman-Ulmer at Innsbruck for enrolling the first subject on the trial! Thank you for helping us reach this milestone.



ROMA Investigator Meeting, Vienna

ENROLLMENT & STUDY STATUS BY SITE

As of February 7, 2018

Region	Site	PI Name	Number of subjects randomized	Subjects in SAG group	Subjects in MAG group
US	Weill Cornell Medicine / NYP Hospital, New York	Gaudino, Mario	1	0	1
Austria	Department of Cardiac Surgery, Innsbruck Medical University	Ruttmann-Ulmer, Elfriede	11	5	6
China	Jilin Heart Hospital	Lemma, Massimo	23	12	11
Italy	European Hospital, Roma,	De Paulis, Ruggero	7	3	4
US	Lennox Hill Hospital, New York	Patel, Nirav	1	0	1

Region	Site	PI Name	Regulatory Status
Germany	Universitätsklinikum Gießen und Marburg GmbH, Giessen	Boening, Andreas	Pending execution of contract
Germany	Universitäts-Herzzentrum Bad Krozingen/Freiburg	Czerny, Martin	Pending execution of contract
Italy	Fondazione Poliambulanza, Brescia	Troise, Gianni PI; Cirillo, Marco (Reg)	Pending execution of contract
China	Fuwai Hospital, Chinese Academy of Medical Sciences	Zheng, Zhe	Pending execution of contract
US	Cleveland Clinic Foundation, Cleveland	Bakaeen, Faisal	Pending execution of contract
Austria	Medical University of Vienna	Sandner, Sigrid	Pending execution of contract
Scotland	Golden Jubilee National Hospital, Clydebank, Glasgow	Spadaccio, Cristiano	Pending execution of contract
Portugal	Center for Cardiothoracic Surgery -Praceta Mota Pinto, Coimbra	Antunes, Manuel	Pending ethics committee approval
Canada - Ontario	Hamilton	Lamy, Andre	Pending ethics committee approval
Taiwan	National Taiwan University Hospital	Chen, Yih-Sharnng	Pending ethics committee approval
China	TEDA International Cardiovascular Hospital (TICH), Tianjin, Chinese Academy of Medical Sciences & Peking Union Medical College	He, Guo-Wei	Pending ethics committee approval

ClinvestiGator



DATABASE REMINDERS

<https://ccim.med.cornell.edu>

- ⇒ Please enter **subject initials** only in the database when randomizing subjects.
- ⇒ To be compliant with privacy rules, a copy of the **informed consent form** must be uploaded into the database for each entered subject.
- ⇒ Please enter the "PID" in the format: 2 digit site number–3 digit subject number (e.g. 01-001).

CONTACT US

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Prof. Nikolaos "Nikos" Bonaros and Prof. Dr. Elfriede "Friedi"

Center Spotlight on: Innsbruck Medical University

"It's left main and aortic dissection season", Prof. Elfriede Ruttmann-Ulmer from the Department of Cardiac Surgery at Innsbruck Medical University and Principle Investigator of the Innsbruck study site of the ROMA trial is describing these days. During winter season, we are really busy like hell with unplanned cardiac surgery procedures and this is very much likely to be associated with the fact that we are one of the top alpine skiing destinations worldwide.

Usually winter sports active people know this area of Tyrol, as Innsbruck has hosted the Olympic Winter Games twice in 1964 and 1976. It is also well known as the "cradle" of alpine skiing that has been invented in our "Arlberg mountains". Moreover, it is well known to all pilots and aircraft engineers from flight simulations, as it requires a special education as a pilot to get an airplane safely down in a valley like this. Furthermore, the airport is almost in the middle of town and only 2 kilometers away from the city center. Additionally, the Medical of University is only a foot-walk away from the "golden roof".

Innsbruck is a small, but marvelous and medieval city with 132.000 inhabitants only but with a long history and approx. 30.000 students studying at our University. However, it is the largest city in western Austria with a medical catchment area of approx. 1.2 million steadily living people from Tyrol, Vorarlberg and South Tyrol.

However, during winter season, our inhabitants are increasing tremendously, as approx. 3.5 million people are steadily living in our "medical catchment area" during this period (mainly as winter sports tourists) and this fact is pushing us somehow to the limits of our Intensive Care Unit capacities.

Innsbruck Spotlight, continued

Acute myocardial infarctions and aortic dissections are at the top list beside traumatic injuries during winter season at our Hospital.

As most tourists are coming from more flat areas with low sea levels, exercise in our high alpine conditions is very much likely to cause acute myocardial infarctions among patients with preexisting coronary artery disease and acute dissections of the aorta.

Our department is treating all facilities of adult cardiac surgery with a heart and lung transplant program and ventricular assist device program, including minimal invasive aortic and mitral valve procedures and a high rate of multiple arterial revascularization procedures. The multiple arterial revascularization rate during the past 17 years was 43% among patients undergoing non-emergent multi-vessel CABG. Moreover, our rate of providing CABG patients with bilateral internal thoracic arteries exceeded the 64% rate in 2016.

In 2015, Mario & David asked me whether I would like to participate in their RADIAL working group and I was tremendously happy to find colleagues that are academically active in this field to do research on CABG. Moreover, in spring 2016, as Mario & Steve asked me to participate in a really big trial on MAR and to be part as a Vanguard center, I guaranteed them to put all my efforts into this trial to make this possible and to get it started. It is a really great honor for our center to be the first that has randomized patient NB 1 for ROMA. We could have done this even earlier, but randomization site was not open yet.

Mario once said that according to ROMA, he has initially nothing else to offer than our passion for CABG. As I am performing a longitudinal follow-up study on MAR patients since 17 years now, I already knew that ROMA may not be very different from what we were already doing since years (like blood, sweat, and tears – but passion and persistence).

Innsbruck Medical University was founded in 1669 by the Habsburg Emperor Leopold the First. Our University is celebrating the 350-year anniversary in 2019!!!!

Below are a few photos from our city. Maybe a great area for a future ROMA trial meeting!!!!

You are warmly welcome,

Best wishes from Innsbruck, AUSTRIA

Friedi



The winter view down to Innsbruck from our "North chain" mountains. Just 40 km away from the Italian border.



World famous architecture too (Zahra Hadid)



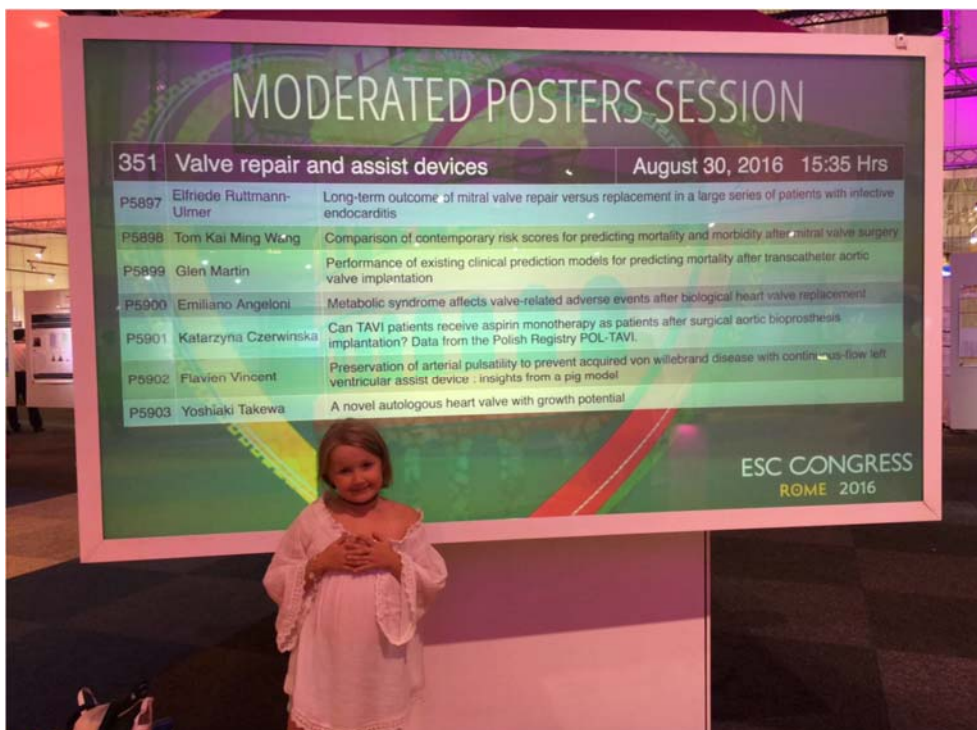
Happy new year from our "Times Square"



You can take the cable car, you can hike up, or you can bike up to the top. I prefer the last !!!!!



Old University building. We are celebrating 350 years in 2019!!!!



That's why I love ROMA and Italy. Even as a Congress venue, and as a "working mom" – I've never ever in my life experienced a more children-friendly congress as the ESC 2016 in ROMA !!!!! I've never experienced a more children friendly country like Italy at all.

I still don't really know yet, whether it was me or our daughter Lillian who won the "Moderated poster prize" at the ESC 2016. While I gave my presentation, our daughter Lillian was sitting next to my slides, as her father was giving a talk as a cardiovascular epidemiologist at the same time!!!!