



XIENCE V SPIRIT WOMEN

Newsletter

August 2009

Reminders

Please help us complete the 30-day database lock activities for the Single-Arm Study by doing the following

- Answer all outstanding queries. Your CRA / RC will follow-up with you to help
- Submit all outstanding source documents for 30-day adverse events either to Abbott Vascular or to your CRA

Query Resolution Tips

- Check queries daily to prevent creating a time-consuming backlog
- Use the QUERIES function in the eCRF
- Weekly data query excel report is available from your CRA / RC if helpful

Activity Highlights

Enrollment Status	Randomized Sub-study
Centers Open	25
Centers Enrolling	23
Patients Enrolled	309
Top 5 Enrollers—August	Swiss Cardiovascular Center Bern (Prof. Windecker, SWI) San Ambrogio (Dr. Bedogni, ITA) Bad Oeynhausen (Dr. Wiemer, GER) Centro Cardiologico Monzino (Prof. Bartorelli, ITA) Latvian Center Cardiology (Dr. Erglis, LAT)
Average Enrollment / Site / Month	2.1
Expected Completion	December 2009

Many thanks to you and your teams for your active contribution to the success of the Study!

We have exceeded our **RSS enrollment goal** for **August**. Congratulations to all study teams!

One new site, **Instituto Dante Pazzanese De Cardiologia (Dr. Abizaid, BRA)**, was activated into the Randomized Sub-study in the month of August.

The ESC Investigator Meeting took place on August 31 in Barcelona. The agenda included an update on the Randomized Sub-study and the ongoing database lock for the Single-Arm Study as well as a refresher training on the central lab procedures and QCA imaging. A more detailed overview of the Investigator Meeting will be included in the September newsletter.

On August 11, we visited **Semmelweis University Hospital (Prof. Merkely, HUN)**, the second center to finish enrollment in the Randomized Sub-study. Over the period of eight months, the center enrolled 45 patients, with the average enrollment rate of 5.8 patients / month. The interview with Prof. Merkely (Principal Investigator), Dr. Szabo (Sub-Investigator) and Dr. Balázs (Research Coordinator) is highlighted on pp. 2 and 3.

The **RSS enrollment goal** for the month of **September** is 345 patients. Please continue to screen and enroll patients so that we not only meet but also exceed this goal.

Semmelweis University Hospital, Hungary

Most of us know little about Hungary. What can you tell us about the heart disease situation in your country?

Prof. Merkely: Like the rest of Eastern Europe, Hungary has a high rate of cardiovascular mortality of more than 50 %. The acute MI rate among people under 65 years old is 2.5 times higher than it is in the EU 15. Other than a genetic predisposition, there are several factors at play. 32 % of the population smokes. The economic crisis also makes a big difference. Eastern Europe has been much impacted by the recent economic turmoil and the unemployment rate is relatively high. For 10 million citizens, we have 16 cardiac clinics, many of which are quite large.

What role does your center play?

Prof. Merkely: Ours is a university clinic and the largest center in Hungary. Every year, we do 6000 catheterizations and 2800 PCIs. With 10 skilled interventional cardiologists and 2 cath labs, we work around the clock and cover 3.5 million citizens.

What does the SPIRIT WOMEN Study mean to you?

Prof. Merkely: A high percentage of our patients are women. I have reviewed our statistics in preparation for this meeting and noticed that 44 % of the recent patients have been women. Women have an even lower chance of getting a job, especially when they are in their late 50s / early 60s, and the rate of heart attack is high. At least 2/3 of all female patients are acute. Given the high number of female patients, it is important for us to understand how to treat them. It is a well-known fact that few female patients participate in randomized studies, and we need to change that.



Prof. Merkely, Principal Investigator

You have enrolled 45 RSS patients in the period of 8 months. What has made you so successful?

Prof. Merkely: We have a very young team, with the average age of 36-37 years old. Our team likes to participate in clinical studies, and we approach them with a high degree of energy. All potential patients are screened. We explain to the patient that we are comparing two proven stents so there is no bad choice. Also we say that patients who take part in a clinical study tend to have better outcomes due to a more structured follow-up and better compliance. We do 90 % of our follow-up angiography through the radial approach which further reduces anxiety. Our acceptance rate is around 2/3.

You have personally treated an impressive number of patients in the Study. What motivates you?

Dr Szabo: PCI in women is an important topic, especially for a center like ours that sees many female patients. Some days, we only have women in the cath lab! I am especially interested in the head-to-head comparison with CYPHER. We have heard so much about third-generation DES being better than the first-generation DES but I would like to get some direct comparison data.



Dr. Szabo, Sub-Investigator

(continued on p. 3)

Semmelweis University Hospital, Hungary (*continued*)

What about challenges? This could not have been an easy journey.

Dr. Balázs: Patient enrollment has not been a big problem but staying on top of the eCRF for 82 patients (37 in SAS and 45 in RSS) has cost me a few sleepless nights! The eCRF is very detailed and time-consuming but I understand it needs to be done. Making sure patient follow-up for so many patients is completed in a timely manner is also a challenge. We use an online spreadsheet to flag when a patient needs to come back. This spreadsheet, with key patient data, is accessible online to all physicians so that they can easily retrieve the information during the follow-up visits. Our first RSS patient is expected to present for the 9-month angiographic visit at the end of September. I will call the patient one month prior to arrange a visit and then contact her again one week before the visit as a reminder.



Dr. Balázs, Research Coordinator



The Team at Semmelweis University Hospital

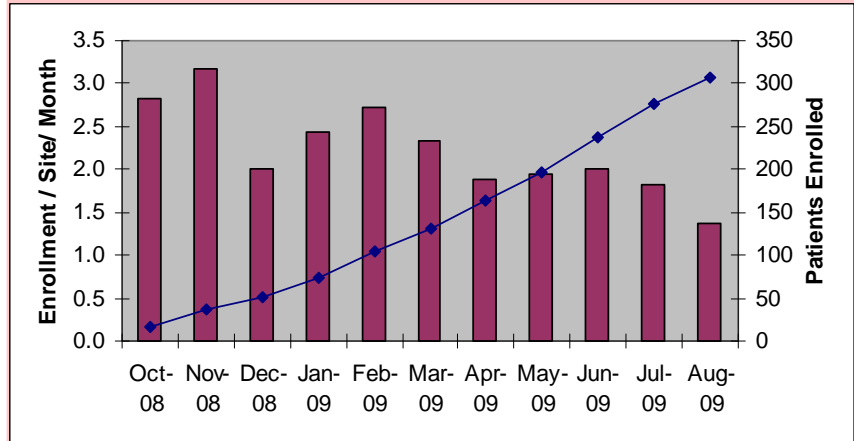
Randomized Sub-study Status

Enrollment by Site

Site	Patients Enrolled	Average Enrollment/Month
Cardiocentro Ticino (Dr. Pasotti, SWI)	45	Enrollment complete
Semmelweis University (Prof. Merkely, HUN)	45	Enrollment complete
ICPS (Dr. Morice, FRA)	35	3.1
Swiss Cardiovascular Ctr Bern (Prof. Windecker, SWI)	20	1.9
Rigshospitalet (Dr. Helqvist, DEN)	18	1.7
San Ambrogio (Dr. Bedogni, ITA)	18	4.0
Latvian Center Cardiology (Dr. Erglis, LAT)	16	2.4
Ospedale di Modena (Prof. Modena, ITA)	13	1.5
Hosp. Trias y Puyol (Dr. Mauri, ESP)	12	1.7
Bad Oeynhausen (Dr. Wiemer, GER)	11	2.6
Institute of Cardiology (Prof. Witkowski, POL)	10	0.9
Hospital Italiano (Dr. Grinfeld, ARG)	10	1.4
Humanitas (Prof. Presbitero, ITA)	11	2.4
Haukeland Univ. Hop. (Dr. Tuset, NOR)	10	1.0
A.O. Universitaria Pisana (Dr. Petronio, ITA)	8	1.6
Klinikum Bad Segeberg (Prof. Richardt, GER)	6	2.0
H. General de Alicante (Dr. Mainar, ESP)	6	2.4
Centro Cardiologico Monzino (Prof. Bartorelli, ITA)	5	0.9
H. H. Ziekenhuis Roeselare (Dr. Stammen, BEL)	3	1.0
Herzzentrum Dresden (Prof. Strasser, GER)	3	1.0
ICBA (Dr. Belardi, ARG)	2	0.6
Allgemeines Krankenhaus Stadt Wien (Prof. Lang, AUT)	2	2.3
St. Antonius (Dr. Suttorp, NED)	1	0.6
AMC (Dr. Piek, NED)	0	0
Inst Dante Pazzanese De Cardiolog (Dr. Abizaid, BRA)	0	0

Site activated on Aug 21

Enrollment / Month / Site



Study Contact Details

If you have any questions about XIENCE V SPIRIT WOMEN, please contact your CRA or one of the two XIENCE V SPIRIT WOMEN Project Managers:

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