



PRAETORIAN

S-ICD vs TV-ICD

News letter d.d. 26 June 2013

General Information

1. International trial manager



This May, Lonneke Smeding has started as International trial manager. Lonneke studied Biomedical Sciences, and obtained her PhD last year in experimental cardiology. She will now be occupied with all affairs concerning the Praetorian Trial. Her contact information can be found below. This summer, she will visit the Dutch sites together with Ingeborg Go.

2. Financial agreements

Starting July 1st, Boston Scientific will finance the Praetorian Trial. Currently we are adding the final touch to the sponsor agreement and the new site agreements. Because of the involvement of Boston, we will be able to increase the reimbursement fee per patient (compared to the current reimbursement). This will be done with retroactive effect; fees will also be increased for already included patients. When the new site agreement is finished, we will send this as soon as possible.

3. Protocol alterations

In order to reach 90% power, we have increased the patient number to 850 (2*425). Moreover, follow up is prolonged from 2.5 to 4 years mean follow-up.

4. Randomization procedure

A small change is made on the randomization website (ALEA). We are required to verify eligibility of a patient prior to randomization. Therefore, on the randomization website questions are added to confirm that the patient meets the inclusion criteria and not the exclusion criteria. Furthermore, the name of the treating physician needs to be entered.

5. Centres (outside NL)

We are in the process of expanding our study to Germany, the United Kingdom and Denmark. We had a successful investigator meeting at the HRS conference in Denver. At least 12 centres have indicated to be willing to participate. Currently we are working on the applications to the ethical committees. We hope this will be done within 2-3 months (however, summer season may cause some delay). When approval is obtained we will again contact the interested centres with further information on how to proceed.

6. Centres (NL)

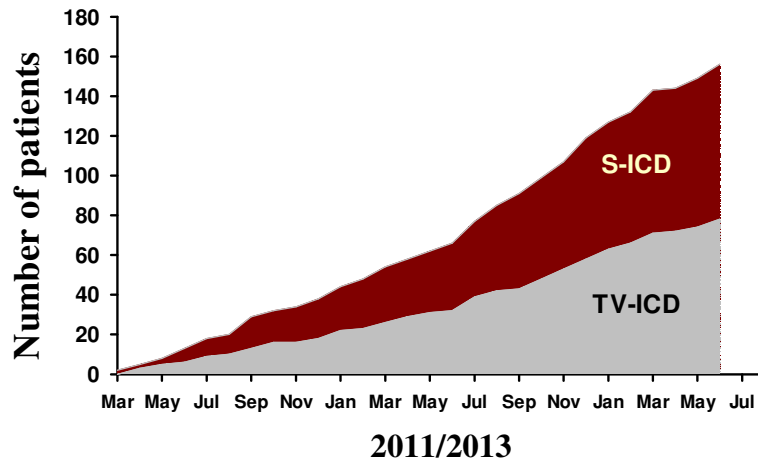
Currently we have 8 centers in the Netherlands participating in the trial, who have at this moment recruited 156 patients in total (see graph below). Also UMC St. Radboud Nijmegen, Catharina Hospital Eindhoven and Thorax Center Twente will start recruitment shortly.

Patients

Inclusion:



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AMC Amsterdam	90
Isala Klinieken Zwolle	29
Flevoziekenhuis Almere	19
St. Antonius Hospital Nieuwegein	7
Amphia Hospital Breda	6
Maastricht UMC	4
Erasmus MC Rotterdam	1
UMC Groningen	0

Contact

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