PRAETORIAN
S-ICD vs TV-ICD

Newsletter

12 March 2018

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Changes in AMC PRAETORIAN Team

In 2018 there are some changes in the AMC PRAETORIAN team.

- Anouk de Weger (left image) has joined our team as Trial Assistent. Please contact Anouk (a.deweger@amc.nl) for questions regarding invoices and Oracle accounts.

- Annelies Vinken is no longer monitoring PRAETORIAN. Annelies was monitoring several PRAETORIAN sites.

- Linde Vertelman (right image); Linde will take over monitoring from Annelies for most sites. Her e-mail address is L.V.vertelman@amc.nl

No Investigator meeting at HRS

PRAETORIAN is currently in its follow up phase. As the interim analysis did not show superiority of the S-ICD, the protocol indicated that follow up will be performed a median of 48 months is reached. As there will be no other interim analysis or protocol updates, there will be no Investigator meeting at HRS this year. Members of the PRAETORIAN team will be present at HRS, and will of course be available to meet you at the conference if you have any questions!

Please use Simplified SOP "Medication Reporting"

As the procedure for reporting of medication was considered quite complicated, we simplified medication reporting in the eCRF last year. Start and stop date only need to be filled out in specific situations. Please use this SOP as it makes your work easier!

SMARTPass switch off visible as untreated episode on print-out

The algorhythm SMARTPass on the S-ICD will automatically switch off if the sensed signal will be too low. This is shown as an 'untreated episode' on the read out, but no EGM will be available. When an untreated episode is shown on the read out, but no EGM can be found, please check if this is due to the SMARTPass being switched off.

Please make sure SMARTPass is being switched 'On' (protocol setting), or enter in the eCRF that switching 'On' is not possible.

S-ICD AF Monitor only available on A219 EMBLEM MRI

In the eCRF, on the follow up page for the S-ICD, the following question is asked: 'AF seen? Yes/No/NA'

The AF monitor is only available on the A2019 EMBLEM MRI S-ICD, therefore, this questions only refers to patients with this device. For all other devices you can select 'AF seen? -> NA'. Also when AF monitor is not programmed ON, you can select NA. Only when the AF monitor was programmed ON, please select if AF was seen.

Study settings are improving

In the past months device settings were corrected again in quite some patients such that currently **86.5% of the devices are programmed correctly** although in 63 S-ICDs SMARTPass needs to be programmed on/activation must still be noted in eCRF.

Activation of SMARTPass in the (EMBLEM) S-ICD is part of the study settings. Please have incorrect settings corrected as this may affect the primary endpoint. Correct settings are also part of the milestones, such that these cannot be paid if settings are incorrect.

Notification of (S)AE

Please let us know as soon as possible when a cardiovascular event or a (treated) arrhythmia episode has occured or when a patient passed away. Please enter the data in the eCRF AND send a short notification to the trial manager Lonneke Smeding at l.smeding@amc.nl and your monitor. More information can be found in the SOP 'Adverse Event Reporting' in the Investigator file.

BEDANKT – DANKE – THANK YOU – TAK – DĚKUJU