CREST (2018-008)

SERIOUS ADVERSE EVENT REPORT

Mail all pages of the reports to: crest.studie@erasmusmc.nl

Patient information			EMC research staff only					
Patient number	_		SAE sequence number Report reviewed by	_ - - - -				
Date of birth [dd/mm/yyyy]			Date review	l				
Report information			•					
Hospital								
Person reporting the SAE								
Type of report		☐ Initial report	☐ Follow up report	☐ Final report				
Date of initial report	[dd/mm/yyyy]							
Date of follow up report								
Date of final report	[dd/mm/yyyy]							
Serious Adverse Event information								
Adverse Event Term								
Diagnosis of Adverse Event in a single term; if no diagnosis is available yet, please provide the most relevant sign or symptom								
Date onset AE	[dd/mm/yyyy]							
Date AE became Serious	[dd/mm/yyyy]							
Reason AE is Serious		1= death	2= life-threatening 3= (pro	longation of) hospitalization				
		4= signifi	cant / persistent disability 5= con	genital anomaly / birth defect				
		6= other	medically important condition					
Date of hospitalization	[dd/mm/yyyy]							
Date of discharge	[dd/mm/yyyy]							
Severity of AE	[CTCAE grade]	<u> </u>						
(Highest grade observed)	mmonte describ	a the source of avents	include dates and results of tests / pro	acaduras / actions taken /dates of				
<u>-</u>			include dates and results of tests / pr	ocedures / actions taken /dates or				
discharge (for final report: outcome of adverse event, test result etc.)								
Treatment Arm and Phase	se							
Treatment arm	<u> </u> _	_ 1= arm A (Int	1= arm A (Intervention group: rehabilitation program)					
		•	2= arm B (Control group: usual care)					
Protocol phase during / after wh	nich the SAE _	_ 0= Before su	0= Before surgery 2= Follow-up					
occurred		1= During Inte	1= During Intervention (4 – 16 weeks after discharge)					

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Patient number:	_ _ _ Date of report _							
□ Initial report	□ Follow up report		□ Final repo	ort				
Possible Causes of SAE Please specify if there are circumstances that may have contributed to the SAE or could help explain the SAE								
Disease under study (inclu	ding progression)			0= No	1= Yes			
Medical condition(s) Any <u>relevant</u> past or current r that could help explain the SA	nedical disorders (not disease under study AE), allergies, surgeries		0= No	1= Yes, specify below			
Concomitant medication(s)			0= No	1= Yes, specify below			
Other				0= No	1= Yes, specify below			
Specification:								
Outcome of SAE		1= resolved	*					
		2= ongoing						
		3= death (ca	aused by SAE)**					
		4= ongoing	at death (death du	ie to anoi	ther cause)**			
		5= ongoing	closed (because s	stable situ	uation reached)			
* Date SAE resolved	[dd/mm/yyyy]							
** Date of death	[dd/mm/yyyy]		[
** Cause of death								
Action taken regarding	the SAE							
Signature for report – the (sub) investigator should always review and sign at least the final report								
Date	Name:	Signature						
Date	Name:	Signature						
Date	Name:	Signature						
Date	Name:	Signature						
Date	Name:	Signature						

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