SA HEART ASSOCIATION/SASCI STEMI EARLY REPERFUSION PROJECT

Delays in early reperfusion for ST-segment-elevation myocardial infarction – an observational multi-centre study in South African hospitals

Patient copy

Dear Patient

We invite you to participate in a research study. This information leaflet will help you to decide whether you would like to participate. Before you agree to take part you should fully understand what participation entails. If you have any questions that this leaflet does not fully explain, please do not hesitate to ask your cardiologist.

THE NATURE AND PURPOSE OF THIS STUDY

The aim of this study is to determine which factors lead to a delay in treatment of a heart attack in Tshwane hospitals. Your history as a patient is a very important source of information on how these delays may be prevented so that in future treatment can commence as soon as possible in patients with heart attacks.

EXPLANATION OF PROCEDURES TO BE FOLLOWED

This study involves the recoding of relevant information of your case by the cardiologist that is treating you. We will ask you some questions about your medical status preceding the heart attack, details of your symptoms, and how you got to hospital. Your diagnosis and treatment will be recorded until you are discharge from the hospital.

RISK AND DISCOMFORT INVOLVED

There are no risks in participating in the study.
The interview will take about 15 minutes of your time.

POSSIBLE BENEFITS OF THIS STUDY

Although you will not benefit directly from the study, the results of the study will enable us to improve the care of patients with heart attacks in future.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Your participation in this study is entirely voluntary. You can refuse to participate or stop at any time during your treatment without giving any reason. Your withdrawal will not affect you or your treatment in any way.

HAS THE STUDY RECEIVED ETHICAL APPROVAL?

This study has received written approval from the Research Ethics Committee of the Faculty of Health Sciences at the University of Pretoria, telephone numbers 012 3541677 / 012 3541330

INFORMATION AND CONTACT PERSON

The contact persons for the study are Prof Rhena Delport and Dr Adriaan Snyders. If you have any questions about the study please contact them at the following telephone numbers: 082 445 4500 or 082 446 1558.

COMPENSATION

Your participation is voluntary. No compensation will be given for your participation .

CONFIDENTIALITY

All information that you give will be kept strictly confidential. Once we have analysed the information no one will be able to identify you as participant. Research reports and articles in scientific journals will not include any information that may identify you, your cardiologist, or the hospitals where you were treated.

CONSENT TO PARTICIPATE IN THIS STUDY

Patient copy

I confirm that the person asking my consent to take part in this study has told me about nature, process, risks, discomforts and benefits of the study. I have also received, read and understood the above written information (Information Leaflet and Informed Consent) regarding the study. I am aware that the results of the study, including personal details, will be anonymously processed into research reports. I am participating willingly. I have had time to ask questions and have no objection to participate in the study. I understand that there is no penalty should I wish to discontinue with the study and my withdrawal will not affect any treatment in any way.

I have received a signed copy of this informed consent agreement.

	Name (Print)	Signature	Date
Participant			
Investigator			
Witness			

VERBAL INFORMED CONSENT

I, the undersigned, have read and have fully explained the participant information leaflet, which explains the nature, process, risks, discomforts and benefits of the study to the participant whom I have asked to participate in the study.

The participant indicates that s/he understands that the results of the study, including personal details regarding the interview will be anonymously processed into a research report. The participant indicates that s/he has had time to ask questions and has no objection to participate in the interview. S/he understands that there is no penalty should s/he wish to discontinue with the study and his/her withdrawal will not affect any treatment in any way. I hereby certify that the client has agreed to participate in this study.

	Name (Print)	Signature	Date
Participant			
Person seeking consent			
Witness			

CONSENT TO PARTICIPATE IN THIS STUDY

Study copy

I confirm that the person asking my consent to take part in this study has told me about nature, process, risks, discomforts and benefits of the study. I have also received, read and understood the above written information (Information Leaflet and Informed Consent) regarding the study. I am aware that the results of the study, including personal details, will be anonymously processed into research reports. I am participating willingly. I have had time to ask questions and have no objection to participate in the study. I understand that there is no penalty should I wish to discontinue with the study and my withdrawal will not affect any treatment in any way.

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	Name (Print)	Signature	Date
Participant			
Person seeking consent			
Witness			

SA HEART SASCI STEMI EARLY REPERFUSION PROJECT

Today's date	
Hospital	
Patient Name	
Patient number	
Contact number	
Cardiologist	

Sticker

CLINICAL EXAMINATION AND HISTORY

Sex				Age	Height	Weight	Waist circumference	Heart rate	Smoking Duration if yes: ..... (years)	Smoker Amount per day	Ex-smoker Amount per day	Never smoked
Male		Female		yrs	cm	kg	cm	/min				

Physical activity	Less than moderate		Moderate 30 min 3 - 5 times / week		More than moderate	

THROMBOLYSIS

Medication prior to Thrombolysis	Dosage		
Asprin		Date	Time
Clopidogrel		Date	Time
Unfractionated Heparin		Date	Time
Ticagrelor		Date	Time
Other		Date	Time
Other		Date	Time
Other		Date	Time

Thrombolytic agent			
Select any	Streptokinase	Tenecteplase	Reteplase
Dosage			
Start date and time		Date	Time
End date and time		Date	Time
90-120minECG		Date	Time
Successful lysis		Yes	No

CARDIAC HISTORY (*If coronaropathy known before the MI*)

Previous MI (1)	Date	DETAIL
Previous MI (2)	Date	DETAIL
Stable AP	Years / mo	COMMENT
CABG	Date	COMMENT
PCI (1)	Date	DETAIL
PCI (2)	Date	DETAIL

DIAGNOSIS

ECG 1 Date and time	**ECG 2** Date and time	**Diagnosis confirmed** Date and time

Chest discomfort Location of Pain	DETAIL							
Pain severity: 0-10	Palpitation	✓	Pallor	✓	Diaphoresis	✓	Shortness of breath	✓
	Nausea/ vomiting	✓	Dizziness	✓	Syncope	✓		

COMORBID CONDITIONS			
Previous IHD	Duration if yes: years/mo		
Family history of premature CVD *1st degree relative <55 years in men or <65 in women*	*Detail*	Unknown *Patient doesn't know*	Unknown *Patient doesn't know*
Hypertension	Duration if yes: years/mo		
Diabetes type 2	Duration if yes: years/mo	Most recent HbA1C: ..... % Fasting glucose ..... mmol/L	Date reported
Diabetes type 1	Duration if yes: years/mo	Most recent HbA1C: ..... % Fasting glucose ..... mmol/L	Date reported
Hypercholesterolemia *Treated hypercholesterolemia or Total LDL chol. > 2,5mmol/L*	Duration if yes: ..... (years)	Total chol. ..... mmol/L LDL chol. ..... mmol/L HDL chol. ..... mmol/L Triglycerides. ..... mmol/L	Date reported

PATIENT JOURNEY									
Event	**Comment**				**Date**		**Time**	**Unknown**	
Symptom onset									
First medical contact (FMC)									
Paramedic	✓	ER at **non**-PCI-capable	✓						
GP consulting room	✓	ER at PCI-capable hospital	✓						
Cardiologist consulting room	✓	Other:	✓						
Strategy with FMC									
Immediate transfer for p-PCI	✓	Fibrinolysis and immediate transfer	✓	Secondary transfer	✓	No reperfusion in acute stage	✓		
Transport intervals									
EMS call to response time		EMS arrival to departure time		EMS transport to hospital time		Personal transport to hospital time			
Total distance travelled to hospital (km)									
Referral pathway									
	Arrival at non-PCI-capable hospital	Name of hospital							
	Departure from non-PCI-capable hospital								
	Arrival at PCI-capable hospital	Name of hospital							
	Admission to	ER							
		ICU							
		Cathlab							
		Other							
	Arrival in Cathlab								

Angioplasty		Date and time
Primary PCI		
Coronary angiography with follow-on PCI in patients presenting within >12 hours of the onset of symptoms		
Coronary angiography with follow-on rescue PCI within 60–90 min after administration of fibrinolytics in patients with failed reperfusion		
Coronary angiography with follow-on rescue PCI in patients with recurrent myocardial ischemia after fibrinolysis		

Treatment of guilty lesion:	No. of DES used (drug-eluting stents)		No. of BMS used (bare metal stents)		No. of Balloons used		No. of GWs used (guide wires)	
Thrombectomy ☐	Aspiration ☐	Balloon only ☐	Simultaneous treatment of other lesions ☐		Thrombolysis intra coronary ☐		Complete revascularisation ☐	
Comments								

Post-PCI	Date and time	Comment
Transfer to ICU		
Transfer to ward		
Transfer to rehabilitation facility		
Transfer to referral hospital		
Discharge from hospital		
Non: Deceased		
Adult smoking advice or counselling given		
Pre-discharge patient education provided		

DISCHARGE MEDICATION

MEDICATION	dosage	MEDICATION	dosage

Comments

Please feel free to add any comments that you feel may be of use in understanding the data collected.
Include information on adverse events, e.g. cardiac arrest ….

Questionnaire completed by	**Contact details**

SA HEART SASCI STEMI EARLY REPERFUSION PROJECT – FOLLOW-UP

Today's date	
Hospital	
Patient Name	
Patient number	
Contact number	
Cardiologist	

Sticker

Follow-up report on first visit

Date:

Follow up report on next visit

Date:

12 Months outcome

Report completed by	Contact details