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| Myocardial infarction, STEMI |
| BEHRNDTZ Pia ([pib@rn.dk](https://webmail.rn.dk/owa/redir.aspx?C=R6Vg5ZusoUSFFaQchXllXoyay_ejqc8Ib7RT5psx1c60QhWpBV_U87u21HNgTJ6MAvG5qsP7zWI.&URL=mailto%3apib%40rn.dk)) |
| February 13, 2013 13:47 PM |

**"How to consent a STEMI patient"**

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**Background and objectives**

Clinical studies should be carried out according to International Conference on Harmonization (ICH) and Good Clinical Practice (GCP) standards. This includes Informed Consent, confirming the subjects’ willingness to participate in a particular trial, after receiving full information (orally and written) of all aspects of the trial, that are of relevance to the subjects’ decision to participation.

STEMI patients, as trial subjects, must be considered vulnerable subjects due to the emergency of the situation, and the circumstances of the illness. It is however necessary to try include these patients in Clinical Trials to continuously develop the STEMI treatment.

Obtaining informed consent from a STEMI patient is a sensitive task considering the circumstances of the illness. Under these circumstances it is only possible to fully inform the patient orally, and hereby secure a signed and dated informed consent form prior to any study related activity.

This pilot project was initiated by the question, whether the STEMI patient who is asked to consider participation in Randomized Clinical Trials (RCT), as a part of the STEMI treatment, can actually relate to the oral information given by the PCI-operator in the Cath. Lab.

It was assumed that several factors influenced on the STEMI patients' attitudes towards participation in RCT.

Hypothesis:

* The STEMI patient might feel pressured to participate in RCT as a part of the treatment.
* It was difficult for the patient to accept participation in RCT when asked to consider participation in more than one RCT at the same time.

Objective:

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| To understand to which extent the STEMI patient felt capable of considering participation in RCT, and what influenced on this decision.  **Methods and results**  This pilot project was set up as a semi-quantitative questionnaire during the patients' admittance to the hospital 6-48 hours after primary PCI.  Questionnaires were delivered to 100 STEMI patients admitted to the hospital during all week, all hours.   Study subjects had the opportunity to answer anonymously, and express their feelings and attitudes towards being asked to consider participation in RCT prior to, and during their treatment for STEMI. Some questions on the questionnaires were designed as yes/no questions, others as a scale to give an intuitive expression of satisfaction and non-satisfaction. In addition it was possible for the subjects to add thoughts and comments.  Results: Will be ready by May 2013.  Conclusions: Will be ready by May 2013 |