Ethical aspects of clinical trials involving acute patients – described in relation to the DANAMI-2 trial

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ABSTRACT

This PhD dissertation is based on five articles and an overview written in the period 2000-2003 while I was employed at The Department of Medical Philosophy and Clinical Theory, Institute of Public Health, University of Copenhagen.

The dissertation concerns ethical aspects of clinical trials involving acute patients, i.e. in particular in relation to the informed consent process. These patients are in a medical condition that gives rise to particular difficulties in relation to the informed consent process. First of all, it is debatable whether acute patients with a serious disease are entirely competent to understand the information and to make a decision since they may be in a state of shock or crisis. Secondly, acute patients have to decide quickly whether or not to participate in a trial and have little time to obtain information and to consider and discuss the options. Finally, under such circumstances the process of informed consent may be distressing to patients, and it is far from self-evident that patients would want to make that kind of decision.

To analyse these issues, an empirical study of patients' perceptions of the informed consent process of a Danish randomised trial, the DANAMI-2 trial, was carried out. This trial involved patients who suffered an acute myocardial infarction (AMI) and who were admitted to an emergency department in the acute phase of the disease.

It was the aim of this dissertation to provide 1) a review of the various enrolment procedures that have been used in earlier AMI trials and 2) a review of earlier studies of the informed consent process in such trials, and 3) to analyse how DANAMI-2 patients experienced the informed consent procedure. On this basis, the dissertation also aimed 4) to analyse the ethical issues of clinical trials involving AMI patients, 5) to provide guidelines for the consent process of future trials involving AMI patients, and 6) to analyse and assess present Danish informed consent legislation in relation to clinical trials involving AMI patients.