STEMI-patients' considerations and attitudes towards participation in Randomized Clinical Trials (RCT)
Behrndtz, Pia; Hass Andersen, Ann; Hald Jørgensen, Helle; Bregendahl, Marianne; Jensen, Svend Eggert

DOI (link to publication from Publisher):
10.1159/000351756

Publication date:
2013

Document Version
Early version, also known as pre-print

Link to publication from Aalborg University

Citation for published version (APA):

General rights
Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

? Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
? You may not further distribute the material or use it for any profit-making activity or commercial gain
? You may freely distribute the URL identifying the publication in the public portal

Take down policy
If you believe that this document breaches copyright please contact us at vbn@aub.aau.dk providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from vbn.aau.dk on: december 11, 2018
Background
RCT in the setting of STEMI is necessary and important.
A STEMI-patient is considered a “Vulnerable Subject” due to the emergency of the situation.
The patient might feel:
• it is a stressful situation
• fear of dying
• pain
• anxiety
• nausea
• separation from loved ones

Methods and Material
• STEMI-patients asked to consider participation in RCT in the Cath.Lab.
• Semi-quantitative questionnarie
• Anonymous
• 24/7
• 6-48 hours after PPCI (in-hospital)
• 100 study subjects

Results
• 96% (96/100) answered the questionnaires
• 94% (94/100) accepted inclusion in RCT
• 78% (69/88) understood information on an acceptable or satisfactory level
• 83% (75/90) participated in RCT to help Clinical Research
• 85% (79/93) are positive about future participation in RCT
• 51% (46/90) state correct the number of RCT in which they participated
• 22% (20/90) underestimated the number of RCT in which they participated
• 9% (8/90) did not know they actually participated in RCT

Conclusion
1. The subjects did not experience pressure to participate in RCT
2. The subjects claimed to understand the given information about RCT on an acceptable or satisfactory level. However only 51% of the participating subjects correctly stated the number of RCT in which they actually participated
3. The subjects participated in RCT primarily to help Clinical Research
4. The subjects are willing to participate in RCT in the future

Hypothesis
• The STEMI-patient feels pressured to participate in RCT
• The STEMI-patient is unable to understand the information about participating in RCT because of the stressful situation

Purpose
To understand to which extent the STEMI-patient feels able to consider participation in RCT, and what has influence on this decision

Patient’s comments
"I feel obligated to help Clinical Research"
"I didn’t dare gamble with my life"
"It was a stressful situation, but it could not be any different, OK."
"I had a lot of pain and didn’t care"
"It happened so fast and I wanted to start treatment immediately"

Limitation
Only a limited number of subjects participated in present study

Future
A larger scale study is planned in order to obtain statistical power

Contact
Pia Behrndtz • pib@rn.dk

Contact
Pia Behrndtz • pib@rn.dk

Contact
Pia Behrndtz • pib@rn.dk

Contact
Pia Behrndtz • pib@rn.dk

Contact
Pia Behrndtz • pib@rn.dk

Contact
Pia Behrndtz • pib@rn.dk

Contact
Pia Behrndtz • pib@rn.dk

Contact
Pia Behrndtz • pib@rn.dk

Contact
Pia Behrndtz • pib@rn.dk

Contact
Pia Behrndtz • pib@rn.dk

Contact
Pia Behrndtz • pib@rn.dk