"Trial-skilled" patients: How big the improvement in cooperation?

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The aim of the study was to evaluate how the participation in trial in the past may improve the level of cooperation between the patient and investigator in the next trial. Methods. The 30 patients with severe persistent bronchial asthma (BA) took part in 2 trials. The indication in both trials was BA. The trials had similar design in features concerning the cooperation of the patient and investigator: using of inhalers, completion of electronic diaries, performing of home peak flowmetry, performing of spirometry in clinic. These parameters were compared in the same patients in the first and in the second trial. The duration of each trial was 1 year. The duration of the period between the trials was 2,1±0,3 months. Data were summarized, using mean, median and standard deviation and range for continuous parameters and using counts and percentages for categorical parameters. Results. In the second trial delay for the visits decreases from 7,7±1,2% to 6,9±1,3% (p>0,05). The returning of the used inhalers became 98,2±4,3% instead of 91,1±5,9% (p=0,04). The compliance for using electronic diaries and performing of the home spirometry increased from 84,2±7,3% to 93,5±6,4% (p=0,034). The present of unacceptable spirometries during the clinic visits decreases from 5,5±0,9% to 3,6±0,5% (p=0,041). Conclusions. It was demonstrated statistically significant improvement in performing of the trial procedures. But initial data were also good and improvement was not so clinically significant in order to choose "trial-skilled" patient instead of "trial-naive" one for enrollment in future trials. In case of worse initial data or bigger experience of the patients in trials this difference may become clinically significant.