

CLINICAL TRIAL GOING ON FOR 10 YEARS – HOW IS IT POSSIBLE?

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Controlled clinical trials of very long duration (more than ten years) are very rare in psychiatry, due to numerous reasons, although it is obvious that these trials can make a substantial contribution to our knowledge regarding maintenance use of particular antipsychotic drugs. Due to the fact that some novel antipsychotics are not yet registered in Croatia (Folnegović-Šmalc et al. 2001, Mimica et al. 2002) and in some other European countries, that is, not available on the market, we still have patients who participate in an open-label extension of a clinical study, taking medication continually under supervision, for more than ten years.

As we are not allowed to speak in detail about ongoing clinical trials, we would like to share our opinion and experience on this matter in general. To be successful in keeping patients for such a long period under clinical trial conditions it is crucial that both patients and investigators should not burn-out. With regard to the patients, it is important that the product under investigation should show great efficacy on positive but also on negative symptoms (Uzun et al. 2006), good tolerability (Mimica & Folnegović-Šmalc 2002) and safety (Folnegović-Šmalc & Mimica 2002), with an optimal side-effect profile (Folnegović-Šmalc et al. 2003a, Folnegović-Šmalc et al. 2003b), which all together should significantly improve patients' quality of life (Kozumplik et al. 2004) and motivate him/her to stay for so long in a trial. We would like to stress that only patients known to have perfect compliance should be enrolled in such studies. For that reason the investigator needs to have a large pool of patients before starting the trial so as to offer him/her the possibility of enrolling suitable patients. For the success of the trial, the local Monitor is very

important, he should be very experienced and willing to help every person involved in the study, to overcome every-day problems and various situations. Keeping all that in mind will help us complete such a demanding task.

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