Sample size is based on the response rate. According to Simon's two-stage minimax design, with a minimum expected response rate of 10%

and an average expected response rate of 30%, a sample of 22 patients

was required in the first step. If a minimum of three responses were

observed it was planned to accrue a total of 33 patients. At the second

phase, if at least seven responses occurred the probability of accepting

an ineffective treatment would be 5%. On the other hand, the risk of

rejecting a treatment with a response rate of more than 30% would be

10% .