Box 1. CONSORT flow diagram

xxx patients were assessed for eligibility
xxx did not meet the inclusion criteria

xxx patients fulfilling inclusion criteria were excluded due to one or several exclusion criteria

xxx patients were randomized

xxx patients were excluded after randomization
  • reasons for exclusion

xxx patients were included in the modified intention to treat population

xxx patients were assigned to 00
xxx patients were analysed for survival until end of trial
xxx were analysed for neurological function at 180 days

xxx patients were included in the per protocol group
  • reasons for being excluded per protocol

xxx patients were assigned to 01
xxx were analysed for survival until end of trial
xxx were analysed for neurological function at 180 days

xxx patients were included in the per protocol group
  • reasons for being excluded per protocol