**Supplementary File**: Assessment of validity of the analyzed studies according to the CONSORT checklist [18] (extended table)

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| Section/Topic | Item number | Neri et al. (2001) | Sakuramoto et al (2007) | Fujimoto et al. (1977) | Douglass et al. (1982) |
| **Title and****Abstract** | 1a 1b | YesNo. No structured summary. | NoYes | NoNo. No structured summary. | NoNo. No structured summary. |
| **Introduction**Background and objectives | 2a2b | YesYes | YesYes | YesYes | YesYes |
| **Methods**Trial designParticipantsInterventionsOutcomesSample sizeRandomizationBlindingStatistical methods | 3a3b4a4b56a6b7a7b8a8b91011a11b12a12b | NoNot applicableYesYesYesYesNot applicableNoNoNo. Method not explained.No. Type not explained.No. Not done.No. Not described. NoYesYesNot applicable | YesYesYesYesYesYesNot applicableYesYesYesNo. Minimization was usedNoNo. Not described. NoYesYesNot applicable | NoNo. Of the 129 cases, 32 patients were discounted because it was too soon for evaluation. YesNoYesYesNot applicableNoNot applicableNo. It is unclear whether or not the study was randomized. No randomization technique is described.NoNoNo. Not described.NoNoNoNo | NoNo. A committee reviewed the eligibility and excluded 12 patients. The investigator excluded 11 more patients. A total of 23 randomized patients were excluded from the analysis.YesNo. YesYesNot applicableNo.Not applicableNo. The method of randomization is not clearly explained. Patients were stratified and then randomized, a power analysis was not includedNoNoNo. Not described.NoYesYesNo |
| **Results**Participant flowRecruitmentBaseline dataNumbers analyzedOutcomes and estimationAncillary analysisHarms | 13a13b14a14b151617a17b1819 | No. In Table 1 of the article only evaluable patients are reported. No information about the number of randomized patients is given.No. Same as 13a. Yes (previous publication)NoYesNoYesNot applicableNot applicableNo | YesYesYesYesYesYes. Main analysis was correctly ITT. Safety analysis was correctly per protocol.YesYesYesYes | No.NoNoNoNo. A Table with demographic characteristics of the analyzed patients is missing.No. ITT analysis was not performed and not enough power was achieved. From the 129 patients included in the intervention group only 97 were analyzed (75%)NoYesNoYes | No.No (see point 3b)YesNoYesNo. ITT analysis was not performed and not enough power was achieved.YesNot applicableNoYes |
| **Discussion**LimitationsGeneralisabilityInterpretation | 202122 | NoNoYes | No. Sponsor was involved in design of trial and collection of dataYesYes | NoNoYes | YesNoYes |
| **Other information**RegistrationProtocolFunding | 232425 | NoNoNo | YesNoNo | NoNoNo | NoNoNo |