|  |  |
| --- | --- |
| **Naam** | **Afstudeerrichting** |
| Referentie (Eerste auteur, titel, bron) |  |
| DOI |  |
| Type publicatie | Type publicatie |
|  |  |
| Conflict of interest? | COI |
| If yes or unclear, explain |
| Describe Patients, Intervention, Control, Outcome in a nutshell | PICO |
| **General design** | |
| Was the trial registered (e.g. Clinicaltrials.gov)? | Trial registration |
|  |  |
| What was the design of the RCT? | Design |
| Was the design appropriately chosen? Comment. | Design appropriate? |
| **Endpoints** | |
| What was the primary endpoint? | Primary endpoint |
| Was the primary endpoint well chosen? Comment. | Comment |
| Secondary endpoints | Secondary endpoints |
| **Sample size calculation** | |
|  | How large was the estimated treatment effect? |
| What was this estimation based on? Was it a realistic and relevant estimation? |
| What were the type I and II error rates? |
| What was the power of the study to detect which treatment effect? |
| What was the required total sample size? |
| **Randomization and blinding** | |
| How and when were patients randomized? | Randomization details |
| Was treatment allocation concealed? Comment. | Treatment allocation blinding |
| Who was blinded for treatment received? Comment. | Blinding |
|  |  |
| **Results and analysis** | |
| Did the authors provide a CONSORT flowchart? |  |
| What was the rate of dropout and crossover in the treatment arms? | Dropout and crossover |
| Where there baseline imbalances between the treatment groups? | Baseline imbalances |
| Were learning curve effects relevant? Comment. | Learning curve |
| Was the required sample size reached? |  |
| What was the size of the treatment effect on the primary outcome? Provide absolute and relative effect size, precision (95%CI), and P value | Treatment effect on primary outcome |
| When applicable, what was the absolute risk reduction and number needed to treat? | ARR and NNT |
| Was normality of data distribution assessed when parametric tests were used? | Data distribution |
| When Cox regression was used, did the authors check the proportional hazards assumption? | Cox PH |
| If subgroups were analysed, were these properly planned, reported, and interpreted? Comment. | Subgroup analyses |
| Were data analysed according to ITT, per protocol, both, or otherwise? Comment. | Intention to treat and/or per protocol analysis |
| **Methodological issues with non randomized trials** | |
| Are there any sources of bias? Refer to the ROBINS-I tool for guidance. | Bias |
| How did the authors correct for confounding? | Statistical method to correct for confounding |
| When multivariate analysis was used: how were independent variables selected? How many events per variable were available? How was model fit estimated? | Details of MV model |
| Did you identify any methodological flaw or error? | Flaw or error |
| **Interpretation** | |
| Is the treatment effect clinically relevant? Comment. | Relevance |
| Are the results applicable to daily practice (external validity)? Comment. | External validity |
| Are the conclusions formulated by the authors based on the data? Is the interpretation of the data correct and unbiased? | Conclusions |
| Will the results affect how you will treat patients? How will you use the data when communicating with your patient? Comment. | Clinical relevance |