The RESOLVE Trial for people with chronic low back pain: statistical analysis plan | Supplemental Material

11/05/2020

### Table A1. Withdrawals (shell)

|  |  |  |  |
| --- | --- | --- | --- |
| Num | Withdrew at… | Reason withdrew | Type of withdrawal |
| 1 | xx | xx | e.g. withdrew consent |
| 2 | xx | xx | e.g. stopped intervention early, provided data at follow-up |
| … | xx | xx | e.g. stopped intervention early, lost to follow-up |
| … | xx | xx | e.g. completed intervention, lost to follow-up |
| n | xx | xx | xx |

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### Table A2. List of all adverse effects reported during the trial (shell)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Description | Intervention, number | Control, number | Severity | Related to trial |
| xx | xx | xx | xx | xx |
| xx | xx | xx | xx | xx |
| xx | xx | xx | xx | xx |

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### Table A3. Engagement with SAP Reporting Guideline a

|  |  |  |  |
| --- | --- | --- | --- |
| Item | Sub-item | Index | Location reported |
| Title | . | 1a | Title |
| Trial registration | . | 1b | Abstract |
| SAP version | . | 2 | Abstract |
| Protocol version | . | 3 | Abstract |
| SAP revisions | . | 4a-c | Not applicable |
| Roles | . | 5 | Title page |
| Signatures | . | 6a-c | Not applicable |
| Background | . | 7 | Introduction |
| Objectives | . | 8 | Introduction |
| Trial design | . | 9 | Methods, trial design |
| Randomisation | . | 10 | Methods, randomisation |
| Sample size | . | 11 | Methods, sample size |
| Framework | . | 12 | Analytic principles, general considerations |
| Interim analyses & stopping guidance | Interim analyses | 13a | Methods, timing of outcome assessments… |
| . | Adjustment for multiplicity | 13b | not applicable |
| . | Stopping guidelines | 13c | not applicable |
| Timing of final analysis | . | 14 | Methods, timing of outcome assessments… |
| Timing of outcome assessments | . | 15 | Methods, timing of outcome assessments… |
| Confidence intervals & P values | Level of significance | 16 | Analytic principles, general considerations |
| . | Adjustment for multiplicity | 17 | Analytic principles, general considerations |
| . | Confidence intervals | 18 | Analytic principles, general considerations |
| Adherence & protocol deviations | Definition of adherence | 19a | Analytic principles, compliance |
| . | Presentation | 19b | Analytic principles, compliance |
| . | Definition of protocol deviation | 19c | Not applicable |
| . | Presentation | 19d | Protocol deviations will be reported in the final manuscript |
| Analysis populations | . | 20 | Analytic principles, general considerations |
| Screening data | . | 21 | Figure 1 |
| Eligibility | . | 22 | Methods, eligibility |
| Recruitment | . | 23 | Methods, follow-up and withdrawal & Figure 1 |
| Withdrawal/follow-up | Level | 24a | Methods, follow-up and withdrawal |
| . | Timing | 24b | Figure 1 |
| . | Presentation | 24c | Table A1 |
| Baseline characteristics | . | 25a, b | Methods, follow-up and withdrawal & Table 1 |
| Outcome definitions | Outcomes and timings | 26a | Analytic principles, outcome definitions |
| . | Measures and units | 26b | Analytic principles, outcome definitions |
| . | Transformations | 26c | Analytic principles, outcome definitions |
| Analysis methods | Methods and presentation | 27a | Analysis & Tables 2 and 3 |
| . | Adjustment for covariates | 27b | None planned |
| . | Assessment of assumptions | 27c | Analysis |
| . | Alternative methods | 27d | Analysis |
| . | Sensitivity Analyses | 27e | None planned |
| . | Subgroup Analyses | 27f | None planned |
| Missing data | . | 28 | Analysis |
| Additional analyses | . | 29 | Analysis, estimating treatment effect with incomplete adherence |
| . | Summary of safety data | 30 | Analysis, adverse effects and serious adverse effects & Table A2 |
| Statistical software | . | 31 | Analytic principles, general considerations |
| References | Non-standard statistical methods | 32a | Analysis & References |
| . | Data-management plan | 32b | Not applicable |
| . | Trial master file | 32c | Not applicable |
| . | Other documents | 32d | Not applicable |

a: Gamble et al. (2017) *JAMA* doi: 10.1001/jama.2017.18556