PROTOCOL ELEMENTS

[1-5] ADMINISTRATIVE INFORMATION

- 1: TITLE
- 2: TRIAL REGISTRATION
  - 2A: REGISTRY
  - 2B: DATA SET
- 3: PROTOCOL VERSION
- 4: FUNDING

- 5: ROLES AND RESPONSIBILITIES
  - 5A: CONTRIBUTORSHIP
  - 5B: SPONSOR CONTACT INFORMATION
  - 5C: SPONSOR AND FUNDER
  - 5D: COMMITTEES

[6-8] INTRODUCTION

- 6: BACKGROUND AND RATIONALE
  - 6A: BACKGROUND AND RATIONALE
  - 6B: CHOICE OF COMPARATORS
- 7: OBJECTIVES
- 8: TRIAL DESIGN


- 9: STUDY SETTING
- 10: ELIGIBILITY CRITERIA
11: INTERVENTIONS

11A: INTERVENTIONS
11B: MODIFICATIONS
11C: ADHERENCE
11D: CONCOMITANT CARE

12: OUTCOMES

13: PARTICIPANT TIMELINE

14: SAMPLE SIZE

15: RECRUITMENT

[16-17] METHODS: ASSIGNMENT OF INTERVENTIONS (FOR CONTROLLED TRIALS)

16: ALLOCATION

16A: SEQUENCE GENERATION
16B: CONCEALMENT MECHANISM

16C: IMPLEMENTATION

17: BLINDING (MASKING)
17A: BLINDING (MASKING)

17B: EMERGENCY UNBLINDING

[18-20] METHODS: DATA COLLECTION, MANAGEMENT, ANALYSIS

18: DATA COLLECTION METHODS

18A: DATA COLLECTION METHODS

18B: RETENTION

19: DATA MANAGEMENT

20: STATISTICAL METHODS

20A: OUTCOMES
20B: ADDITIONAL ANALYSES
• 20C: ANALYSIS POPULATION AND MISSING DATA

[21-23] METHODS: MONITORING

• 21: DATA MONITORING
  • 21A: FORMAL COMMITTEE
  • 21B: INTERIM ANALYSIS

• 22: HARS

• 23: AUDITING

[24-31] ETHICS AND DISSEMINATION

• 24: RESEARCH ETHICS APPROVAL
• 25: PROTOCOL AMENDMENTS
• 26: CONSENT OR ASSENT
  • 26A: CONSENT OR ASSENT
  • 26B: ANCILLARY STUDIES
• 27: CONFIDENTIALITY
• 28: DECLARATION OF INTERESTS
• 29: ACCESS TO DATA
• 30: ANCILLARY AND POST-TRIAL CARE

• 31: DISSEMINATION POLICY
  • 31A: TRIAL RESULTS
  • 31B: AUTHORSHIP
  • 31C: REPRODUCIBLE RESEARCH

[32-33] APPENDICES

• 32: INFORMED CONSENT MATERIALS

• 33: BIOLOGICAL SPECIMENS