**APPENDIX A**:

Sample Schedule of

Study Visits and Evaluation

**SAMPLE SCHEDULE OF STUDY VISITS AND EVALUATION**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Visit Description** | **Screening** | **Treatment and Follow-up** | | | | | | |
| **Study Visits/ Study days (or weeks)** | **Visit -1**  **Day -14 to**  **Day -1** | **Visit 1**  **Day 0**  **Randomization** | **Visit 2**  **Week 2** | **Visit 3**  **Week 4** | **Visit 4**  **Crossover**  **Week 8** | **Visit 5**  **Week 10** | **Visit 6**  **Week 12** | **Visit 7**  **Week 16**  **End of Study** |
| Informed Consent | X |  |  |  |  |  |  |  |
| Demographics |  |  |  |  |  |  |  |  |
| Joint Exam |  | X |  |  | X |  |  | X |
| Medical History | X | X | X | X | X | X | X | X |
| Prior Medications | X |  |  |  |  |  |  |  |
| Physical Exam | X |  |  |  |  |  |  | X |
| Blood Pressure | X | X | X | X | X | X | X | X |
| Height | X | X | X | X | X | X | X | X |
| Weight | X | X | X | X | X | X | X | X |
| Muscle Strength Test | X | X | X | X | X | X | X | X |
| Chemistries | X | X |  | X | X | X | X | X |
| Liver and Kidney Function  Tests | X | X | X | X | X | X | X | X |
| Hematology | X | X | X | X | X | X | X | X |
| Pregnancy Test | X | X |  |  | X | X | X | X |
| Randomization |  | X |  |  |  |  |  |  |
| Intervention Administration |  | X | X | X | X | X | X |  |
| Concomitant Medications | X | X | X | X | X | X | X | X |
| Adverse Events |  | X | X | X | X | X | X | X |
| Study Completion |  |  |  |  |  |  |  | X |