| Adverse Event/Symptom | Minerva Single-Arm Study | Minerva Randomized Study | |
|---|---|---|---|
| | Minerva (n=110) | Minerva (n=102) | Rollerball (n=51) |
| **Intra-operative Adverse Events** | | | |
| Skin Rash and/or Itching or Burning Sensation | 0 (0.0%)** | 1 (1.0%) | 0 (0.0%) |
| **Post-operative Adverse Events (< 24 hours) *** ** | | | |
| Pelvic Cramping | 64 (58.2%) | 51 (50.0%) | 23 (45.1%) |
| Vaginal Discharge and/or Unpleasant Vaginal Smell or Burning or Other Abnormal Sensation | 15 (13.6%) | 32 (31.4%) | 16 (31.4%) |
| Bleeding or Spotting | 8 (7.3%) | 39 (38.2%) | 15 (29.4%) |
| Nausea and/or Vomiting | 17 (15.5%) | 17 (16.7%) | 7 (13.7%) |
| Weakness, Fatigue, Sleepiness, Lack of Concentration, Dizziness | 6 (5.5%) | 5 (4.9%) | 1 (2.0%) |
| Abdominal Pain and/or Bloating | 10 (9.1%) | 0 (0.0%) | 0 (0.0%) |
| Circulatory Symptoms | 4 (3.6%) | 5 (4.9%) | 3 (5.9%) |
| Headache | 4 (3.6%) | 0 (0.0%) | 2 (3.9%) |
| Backache | 3 (2.7%) | 1 (1.0%) | 0 (0.0%) |
| Fever | 0 (0.0%) | 1 (1.0%) | 0 (0.0%) |
| Agitation | 0 (0.0%) | 1 (1.0%) | 2 (3.9%) |
| Vaginal Itching | 0 (0.0%) | 1 (1.0%) | 0 (0.0%) |
| Urinary Disturbance | 0 (0.0%) | 1 (1.0%) | 1 (2.0%) |
| **Post-operative Adverse Events (≥ 24 hours – 2 Weeks) *** ** | | | |
| Pelvic Cramping | 12 (10.9%) | 0 (0.0%) | 0 (0.0%) |
| Abdominal Pain and/or Bloating | 1 (0.9%) | 3 (2.9%) | 1 (2.0%) |
| Nausea and/or Vomiting | 1 (0.9%) | 0 (0.0%) | 1 (2.0%) |
| Vaginal Discharge and/or Unpleasant Vaginal Smell or Burning or Other Abnormal Sensation | 0 (0.0%) | 1 (1.0%) | 0 (0.0%) |
| Weakness, Fatigue, Sleepiness, Lack of Concentration, Dizziness | 0 (0.0%) | 1 (1.0%) | 1 (2.0%) |
| Circulatory Symptoms | 1 (0.9%) | 0 (0.0%) | 0 (0.0%) |
| Constipation | 1 (0.9%) | 0 (0.0%) | 1 (2.0%) |
| Pelvic Inflammatory Disease | 1 (0.9%) | 0 (0.0%) | 0 (0.0%) |
| Fever | 1 (0.9%) | 0 (0.0%) | 0 (0.0%) |
| Uterus Infection | 0 (0.0%) | 1 (1.0%) | 2 (3.9%) |
| Skin Rash and/or Itching or Burning Sensation | 0 (0.0%) | 1 (1.0%) | 1 (2.0%) |
| **Post-operative Adverse Events** | **>2 Weeks – 1 Year** | **>2 Weeks – 4 Weeks†** | |
| Abdominal Pain and/or Bloating | 0 (0.0%) | 0 (0.0%) | 1 (2.0%) |