|  | **Intervention (N₁=30)** | | | **Placebo (N₂=32)** | | | **Treatment Effect Estimate (IRR)** | **95% CI** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| At least one event | Number of events | | At least one event | Number of events | |
| Body system class | N (%) | n (IR) | Mean number of events per participant (SD) | N (%) | n (IR) | Mean number of events per participant (SD) |
| Blood and lymphatic | 23 (76.7%) | 68 (6.3%) | 3 (1.1) | 31 (96.9%) | 90 (5.6%) | 2.9 (1.9) | 1.120 | (0.812, 1.56) |
| Dermatological | 7 (23.3%) | 14 (3.9%) | 2 (1.4) | 8 (25.0%) | 9 (2.4%) | 1.1 (0.4) | 1.350 | (0.544, 3.37) |
| Eyes, ear, nose, throat | 3 (10.0%) | 3 (2.2%) | 1 (0) | 3 (9.4%) | 3 (1.9%) | 1 (0) | 0.433 | (0.00857, 21.9) |
| Gastrointestinal | 16 (53.3%) | 29 (3.5%) | 1.8 (1) | 26 (81.2%) | 65 (4.6%) | 2.5 (1.6) | 0.774 | (0.494, 1.21) |
| Infection | 5 (16.7%) | 7 (3.8%) | 1.4 (0.9) | 1 (3.1%) | 1 (1.6%) | 1 (NA) | 3.740 | (0.181, 77.2) |
| Neurological | 7 (23.3%) | 14 (4.0%) | 2 (1.8) | 6 (18.8%) | 15 (5.4%) | 2.5 (2) | 0.667 | (0.301, 1.48) |
| Other | 12 (40.0%) | 13 (2.2%) | 1.1 (0.3) | 7 (21.9%) | 10 (2.6%) | 1.4 (0.5) | 0.811 | (0.313, 2.1) |
| Psychiatric | 4 (13.3%) | 10 (4.4%) | 2.5 (2.4) | 3 (9.4%) | 4 (2.7%) | 1.3 (0.6) | 1.990 | (0.592, 6.7) |
| Renal and urinary | 1 (3.3%) | 3 (5.3%) | 3 (NA) | 4 (12.5%) | 6 (2.5%) | 1.5 (1) | 3.360 | (0.549, 20.6) |
| Respiratory | 1 (3.3%) | 1 (1.8%) | 1 (NA) | 4 (12.5%) | 5 (2.3%) | 1.2 (0.5) | 0.470 | (0.0353, 6.26) |