|  | **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 (1.8) | 3 (1.1) | 31 (96.9%) | 90 (1.8) | 2.9 (1.9) | 0.930 | (0.668, 1.29) |
| Dermatological | 7 (23.3%) | 14 (0.4) | 2 (1.4) | 8 (25.0%) | 9 (0.2) | 1.1 (0.4) | 1.510 | (0.657, 3.66) |
| Eyes, ear, nose, throat | 3 (10.0%) | 3 (0.1) | 1 (0) | 3 (9.4%) | 3 (0.1) | 1 (0) | 1.150 | (0.205, 6.5) |
| Gastrointestinal | 16 (53.3%) | 29 (0.8) | 1.8 (1) | 26 (81.2%) | 65 (1.3) | 2.5 (1.6) | 0.497 | (0.315, 0.766) |
| Infection | 5 (16.7%) | 7 (0.2) | 1.4 (0.9) | 1 (3.1%) | 1 (0) | 1 (NA) | 6.160 | (1.1, 115) |
| Neurological | 7 (23.3%) | 14 (0.4) | 2 (1.8) | 6 (18.8%) | 15 (0.3) | 2.5 (2) | 1.000 | (0.473, 2.12) |
| Other | 12 (40.0%) | 13 (0.3) | 1.1 (0.3) | 7 (21.9%) | 10 (0.2) | 1.4 (0.5) | 1.790 | (0.761, 4.36) |
| Psychiatric | 4 (13.3%) | 10 (0.3) | 2.5 (2.4) | 3 (9.4%) | 4 (0.1) | 1.3 (0.6) | 2.340 | (0.773, 8.64) |
| Renal and urinary | 1 (3.3%) | 3 (0.1) | 3 (NA) | 4 (12.5%) | 6 (0.1) | 1.5 (1) | 0.509 | (0.106, 1.99) |
| Respiratory | 1 (3.3%) | 1 (0) | 1 (NA) | 4 (12.5%) | 5 (0.1) | 1.2 (0.5) | 0.205 | (0.0106, 1.32) |