1. Subjects’ disposition - Enrolled set

| **Parameter** | **Overall n (%)** |
| --- | --- |
| Enrolled | 39 |
| Enrolled but not randomised1 | 3 (7.7) |
| Randomised1 | 36 (92.3) |
| Discontinued before treatment2 | 0 (0) |
| Treated2 | 36 (100) |
| Completed3 | 36 (100) |
| Discontinued3 | 0 (0) |
| Adverse event3 | 0 (0) |
| Withdrawal by subject3 | 0 (0) |
| Note: The number and the proportion of subjects of each disposition event are reported | |
| Source: Listing 16.2.4.1: Disposition of enrolled subjects  Program: Tables\_ds\_tbl.Rmd | |
| 1Note 1: The denominator for calculating the proportion is the number of enrolled subjects | |
| 2Note 2: The denominator for calculating the proportion is the number of randomized subjects | |
| 3Note 3: The denominator for calculating the proportion is the number of randomized and treated subjects | |

1. Analysis sets - Enrolled set

| **Parameter** | **CHL 3% gel** | **Vehicle** | **Overall** |
| --- | --- | --- | --- |
| **n (%)** | **n (%)** | **n (%)** |
| Safety set | 27 (69.2) | 9 (23.1) | 36 (92.3) |
| Note:  Subjects are summarised according to the product they were assigned to.  The number and the proportion of subjects included in the safety set are reported.  The denominator for calculating the proportions is the number of subjects in the enrolled set. | | | |
| Source: Listing 16.2.4.2: Analysis sets for randomized subjects  Program: Tables\_ds\_tbl.Rmd | | | |

1. Demographic statistics – Enrolled set and Safety set

| **Parameter** | **Categories** | **Statistic** | **Enrolled analysis set** | **Safety analysis set** |
| --- | --- | --- | --- | --- |
| Sex | F | N (%) | 21 (53.8) | 19 (52.8) |
| M | N (%) | 18 (46.2) | 17 (47.2) |
| Age |  | N | 39 | 36 |
|  | Mean | 25.5 | 25.7 |
|  | Median | 25.0 | 25.0 |
|  | SD | 5.4 | 5.5 |
|  | Min | 18 | 18 |
|  | Max | 46 | 46 |
| Body Mass Index |  | N | 39 | 36 |
|  | Mean | 23.3 | 23.3 |
|  | Median | 23.0 | 23.0 |
|  | SD | 3.0 | 3.1 |
|  | Min | 17.6 | 17.6 |
|  | Max | 33.1 | 33.1 |
| Height |  | N | 39 | 36 |
|  | Mean | 175.8 | 175.6 |
|  | Median | 177.0 | 176.0 |
|  | SD | 10.2 | 10.3 |
|  | Min | 160 | 160 |
|  | Max | 193 | 193 |
| Weight |  | N | 39 | 36 |
|  | Mean | 72.0 | 72.0 |
|  | Median | 72.0 | 71.0 |
|  | SD | 11.4 | 11.4 |
|  | Min | 53 | 53 |
|  | Max | 100 | 100 |
| Note:  The number and the proportion of subjects of each sex are reported. The denominator for calculation of the proportions is the number of subjects in each analysis set. | | | | |
| Source: Listing 16.2.4.3: Demography  Program: Tables\_dm\_tbl.Rmd | | | | |

1. Demographic statistics by dose group – Safety set

| **Parameter** | **Group** | **Categories** | **Statistic** | **Safety analysis set** |
| --- | --- | --- | --- | --- |
| Sex | Group 1 (1 drop) | F | N (%) | 6 (50) |
| M | N (%) | 6 (50) |
| Group 2 (3 drops) | F | N (%) | 6 (50) |
| M | N (%) | 6 (50) |
| Group 3 (3 + 3 drops) | F | N (%) | 7 (58.3) |
| M | N (%) | 5 (41.7) |
| Age | Group 1 (1 drop) |  | N | 12 |
|  | Mean | 26.4 |
|  | Median | 25.5 |
|  | SD | 6.6 |
|  | Min | 20 |
|  | Max | 46 |
| Group 2 (3 drops) |  | N | 12 |
|  | Mean | 24.4 |
|  | Median | 24.0 |
|  | SD | 3.3 |
|  | Min | 21 |
|  | Max | 33 |
| Group 3 (3 + 3 drops) |  | N | 12 |
|  | Mean | 26.2 |
|  | Median | 25.0 |
|  | SD | 6.2 |
|  | Min | 18 |
|  | Max | 39 |
| Body Mass Index | Group 1 (1 drop) |  | N | 12 |
|  | Mean | 23.5 |
|  | Median | 22.9 |
|  | SD | 3.4 |
|  | Min | 17.6 |
|  | Max | 30.5 |
| Group 2 (3 drops) |  | N | 12 |
|  | Mean | 22.5 |
|  | Median | 22.8 |
|  | SD | 2.1 |
|  | Min | 19 |
|  | Max | 26 |
| Group 3 (3 + 3 drops) |  | N | 12 |
|  | Mean | 23.9 |
|  | Median | 23.5 |
|  | SD | 3.6 |
|  | Min | 19.6 |
|  | Max | 33.1 |
| Height | Group 1 (1 drop) |  | N | 12 |
|  | Mean | 175.3 |
|  | Median | 176.5 |
|  | SD | 8.8 |
|  | Min | 163 |
|  | Max | 193 |
| Group 2 (3 drops) |  | N | 12 |
|  | Mean | 176.2 |
|  | Median | 177.0 |
|  | SD | 11.1 |
|  | Min | 160 |
|  | Max | 190 |
| Group 3 (3 + 3 drops) |  | N | 12 |
|  | Mean | 175.2 |
|  | Median | 172.5 |
|  | SD | 11.8 |
|  | Min | 160 |
|  | Max | 192 |
| Weight | Group 1 (1 drop) |  | N | 12 |
|  | Mean | 72.3 |
|  | Median | 72.5 |
|  | SD | 10.7 |
|  | Min | 54 |
|  | Max | 85 |
| Group 2 (3 drops) |  | N | 12 |
|  | Mean | 70.2 |
|  | Median | 70.0 |
|  | SD | 11.6 |
|  | Min | 53 |
|  | Max | 87 |
| Group 3 (3 + 3 drops) |  | N | 12 |
|  | Mean | 73.4 |
|  | Median | 69.0 |
|  | SD | 12.8 |
|  | Min | 60 |
|  | Max | 100 |
| Note:  The number and the proportion of subjects of each sex are reported. The denominator for calculation of the proportions is the number of subjects in the safety set. | | | | |
| Source: Listing 16.2.4.3: Demography  Program: Tables\_dm\_tbl.Rmd | | | | |