**Table 1: Characteristics of patients at baseline**

|  |  |  |
| --- | --- | --- |
| **Characteristic** | **Cytisine**  **(N=1239)** | **Placebo**  **(N=1233)** |
| Age (years) a | 42.5 ± 14.3 | 42.4 ±14.2 |
| Male b | 1227 (99) | 1221 (99) |
| Body Mass Index (BMI)a c | 18.5 ± 3.1 | 18.6 ±3.3 |
| Marital status b |  |  |
| Single | 155 (13) | 163 (13) |
| Separated | 2 (0.2) | 6 (0.5) |
| Married | 1067 (86) | 1044 (85) |
| Divorced | 1 (0.1) | 3 (0.2) |
| Widowed | 14 (1) | 17 (1) |
| TB Score b d |  |  |
| Severity Class I | 130 (11) | 134 (11) |
| Severity Class II | 587 (47) | 570 (46) |
| Severity Class III | 508 (41) | 514 (42) |
| Severity Class IV | 14 (1) | 15 (1) |
| Forms of tobacco use (combinations possible) b |  |  |
| Cigarettes | 1152 (93) | 1149 (93) |
| Bidi | 129 (10) | 130 (11) |
| Hookah | 46 (4) | 48 (4) |
| Electronic cigarettes | 1 (0.1) | 2 (0.2) |
| Smokeless tobacco | 82 (7) | 88 (7) |
| Other | 35 (3%) | 28 (2) |
| Cigarettes smoked per day a e | 11.1 ± 8.1 | 11.0 ± 9.0 |
| Duration of smoking (years) a | 23.4 ± 14.2 | 23.3 ± 13.8 |
| Ever attempted to quit in the past b | 324 (26) | 330 (27) |
|  |  |  |
| Strength of urges to smoke in past 24 hours (0- not at all to 5 - all the time) a f | 2.8 ± 1.1 | 2.8 ± 1.1 |
| Tobacco dependence (time to first daily tobacco smoke)b g h |  |  |
| within 5 minutes | 348 (28) | 332 (27) |
| within 5 to 30 minutes | 426 (34) | 418 (34) |
| within 31 to 60 minutes | 217 (18) | 220 (18) |
| after 60+ minutes | 246 (20) | 262 (21) |

a Mean ± SD

b N (%)

c Missing BMI: Cytisine n=2, Placebo n=1;

d TB score was based on the presence of TB related signs and symptoms (e.g. chest pain) and being underweight, with a score of 0 to 8, a higher score indicating a greater number of signs and symptoms present [16](https://paperpile.com/c/RgKhRu/hD2B6)

e Missing cigarettes smoked per day: Cytisine n=91, Placebo n=84;

f Missing strength of urges to smoke: Cytisine n=1, Placebo n=0;

g Tobacco dependence was measured using the second component of the Heaviness to Smoke Index: ‘Time to first use of tobacco product after waking’[17](https://paperpile.com/c/RgKhRu/d5AXV)

h Missing tobacco dependence: Cytisine n=2, Placebo n=1

**Table 2: Effect of cytisine on smoking cessation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Outcome** | **Cytisine**  **(N = 1239)**  **number (%)** | **Placebo**  **(N = 1233)**  **number (%)** | **Percentage-Risk Difference (95% CI)** | **Risk Ratio**  **(95% CI)** |
| Continuous abstinence\*\* |  |  |  |  |
| 6 month |  |  |  |  |
| self-reported | 675 (54.5) | 644 (52.2) | 2.25%  (-1.68 to 6.18) | 1.04  (0.97 to 1.12) |
| biochemically verified (primary outcome)\* | 401 (32.4) | 366 (29.7) | 2.68%  (-0.96 to 6.33) | 1.09  (0.97 to 1.23) |
| 12 month |  |  |  |  |
| self-reported | 600 (48%) | 585 (47%) | 0.98  (-2.96 to 4.92) | 1.02  (0.94 to 1.11) |
| biochemically verified | 309 (25%) | 275 (22%) | 2.64  (-0.71 to 5.52) | 1.12  (0.95 to 5.98) |
| Point Abstinence  (self-reported) |  |  |  |  |
| 5 week | 762 (62%) | 704 (57%) | 4.40  (0.54 to 8.27) | 1.08  (1.01 to 1.15) |
| 12 week | 685 (55%) | 643 (52%) | 3.14  (-0.79 to 7.07) | 1.06  (0.99 to 1.14) |
| 6 month | 509 (41%) | 452 (37%) | 4.42  (0.58 to 8.26) | 1.12  (1.01 to 1.24) |
| 12 month | 426 (34%) | 383 (31%) | 3.32  (-0.38 to 7.02) | 1.11  (0.99 to 1.24) |

\* The primary outcome was continuous, biochemically verified abstinence for 6 months post randomisation, according to Russell Standard Criteria.

\*\* Abstinence was based on smoked and smokeless tobacco use at 6 months. Of those who reported smoked only tobacco use at baseline and had not quit by 6 months (n=839), 7% reported smoked and smokeless tobacco use and 7% reported smokeless tobacco only use at 6 months

**Table 3: TB Treatment success**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cytisine** | | | **Placebo** | | |
| **Time / Outcome Classification** | **N** | **% of available data** | **% total randomised** | **N** | **% of available data** | **% total randomised** |
| Cured or completed treatment at 6 months | 1007 | 89.5% | 81.3% | 1018 | 91.2% | 82.6% |
| Cured or completed treatment at 12 months | 899 | 81.4% | 72.6% | 927 | 83.0% | 75.2% |

**Table 4: Serious Adverse Events summary**

|  |  |  |
| --- | --- | --- |
|  | **Cytisine**  **(N=1239)** | **Placebo**  **(N=1233)** |
| Total number of SAEs | 94 | 90 |
| Possibly/probably related to study drug | 0 | 0 |
| Patients with one or more SAE | 53 (4.3%) | 46 (3.7%) |
| SAE in 10 or more individuals: |  |  |
| Deaths | 49 (4.0%) | 42 (3.4%)) |
| Lung cancer | 9 (0.7%) | 6 (0.5%) |
| Myocardial Infarction | 8 (0.6%) | 5 (0.4%) |
| Difficulty Breathing | 4 (0.3%) | 6 (0.5%) |