Patients enrolled (n=224)

Patients excluded (n=75)

Patients randomised (n=149)

- Placebo Respimat®
  - Treated set (n=144)
  - Full analysis set (n=144)

- Tiotropium Respimat®
  - 5 µg
    - Treated set (n=146)
    - Full analysis set (n=145)
    - Missing efficacy data (n=1)
  - 2.5 µg
    - Treated set (n=147)
    - Full analysis set (n=147)
  - 1.25 µg
    - Treated set (n=146)
    - Full analysis set (n=146)

- Tiotropium Respimat®
  - 5 µg
    - Treated set (n=146)
    - Full analysis set (n=145)
    - Missing efficacy data (n=1)

Discontinued treatment (n=3; 2.1%)
- Premature discontinuation due to adverse event (n=1; 0.7%)
- Lost to follow-up (n=1; 0.7%)
- Consent withdrawn (n=1; 0.7%)

Discontinued treatment (n=3; 2.0%)
- Consent withdrawn (n=2; 1.4%)
- Other (n=1; 0.7%)

Discontinued treatment (n=2; 1.4%)
- Lost to follow-up (n=1; 0.7%)
- Other (n=1; 0.7%)

Discontinued treatment (n=0)

Completed (n=141; 94.6%)