Patients enrolled: N=766

Patients excluded: N=153
- Incorrect enrolment: N=96
- Adverse event: N=17
- Voluntary discontinuation: N=32
- Severe protocol non-compliance: N=1
- Other: N=7

Patients randomized: N=613

Placebo N=208

Formoterol 4.5 µg bid N=206

Formoterol 9 µg bid N=199

Patients discontinued: N=22
- Adverse event: N=10
- Voluntary discontinuation: N=11
- Lost to follow-up: N=12

Randomized

Placebo N=186

Formoterol 4.5 µg bid N=195

Formoterol 9 µg bid N=182

Completed

Patients discontinued: N=11
- Adverse event: N=6
- Voluntary discontinuation: N=4
- Severe protocol non-compliance: N=1

Patients discontinued: N=17
- Adverse event: N=8
- Voluntary discontinuation: N=6
- Lost to follow-up: N=2
- Other: N=1