Screened
N = 775

Randomized
N = 574

Screen Failures
N = 201

Randomized
300 IR
N = 284

Placebo
N = 290

No treatment received
N = 1

Treated
300 IR
N = 283

Discontinued n = 30
Adverse event 14
Consent withdrawn 8
Lack of compliance 3
Investigator Request 1
Pregnancy 1
Other reason 3

Completed Period 1
N = 253

Started Period 2
N = 253

Discontinued n = 10
Adverse event 3
Consent withdrawn 3
Lack of compliance 3
Other reason 1

Completed Study
N = 243
(85.6% of randomized patients)

Randomized
Placebo
N = 289

Treated
Placebo
N = 289

No treatment received
N = 1

Discontinued n = 9
Adverse event 3
Consent withdrawn 2
Lack of efficacy 1
Pregnancy 2
Other reason 1

Completed Period 1
N = 262

Started Period 2
N = 262

Discontinued n = 27
Adverse event 9
Consent withdrawn 7
Lack of compliance 5
Lost to follow-up 1
Lack of efficacy 1
Pregnancy 1
Other reason 3

Completed Study
N = 253
(87.2% of randomized patients)