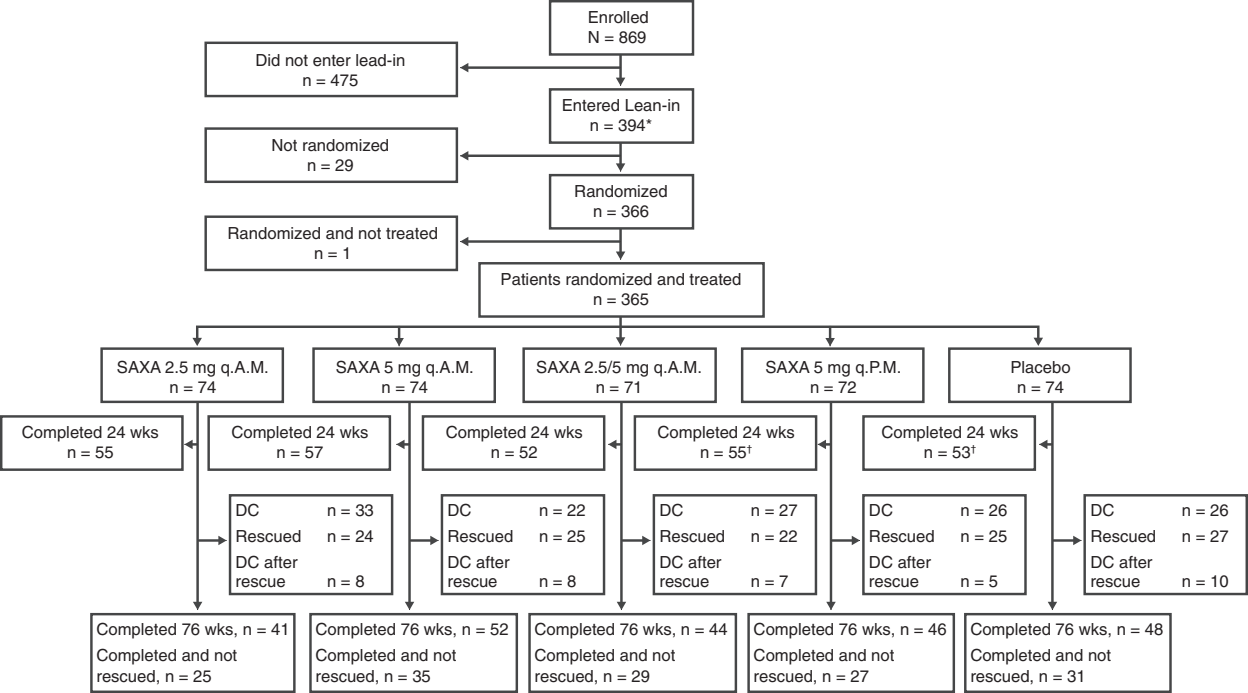
Enrolled
N = 869
Did not enter lead-in
n = 475
Entered Lean-in
n = 394*
Not randomized
n = 29
Randomized
n = 366
Randomized and not treated
n = 1
Patients randomized and treated
n = 365
SAXA 2.5 mg q.A.M.
n = 74
SAXA 5 mg q.A.M.
n = 74
SAXA 2.5/5 mg q.A.M.
n = 71
SAXA 5 mg q.P.M.
n = 72
Placebo
n = 74
Completed 24 wks
n = 55
Completed 24 wks
n = 57
Completed 24 wks
n = 52
Completed 24 wks
n = 55†
Completed 24 wks
n = 53†
DC n = 33
Rescued n = 24
DC after rescue n = 8
DC n = 22
Rescued n = 25
DC after rescue n = 8
DC n = 27
Rescued n = 22
DC after rescue n = 7
DC n = 26
Rescued n = 25
DC after rescue n = 5
DC n = 26
Rescued n = 27
DC after rescue n = 10
Completed 76 wks, n = 41
Completed and not rescued, n = 25
Completed 76 wks, n = 52
Completed and not rescued, n = 35
Completed 76 wks, n = 44
Completed and not rescued, n = 29
Completed 76 wks, n = 46
Completed and not rescued, n = 27
Completed 76 wks, n = 48
Completed and not rescued, n = 31