Assessed for eligibility (n=747)

Randomized (n=225)

Allocated to SC placebo + oral indomethacin (n=76) Treated (n=76)
  Withdrawed (n=8 [10.5%])
    Protocol noncompliance n=0
    Adverse event n=2
    Lack of efficacy n=2
    Request by subject n=2
    Lost to follow-up n=1
    Death n=0
    Other n=1
  Analysed (n=75)
    Completed (n=68 [89.5%])

Allocated to SC rilonacept + oral indomethacin (n=74) Treated (n=74)
  Withdrawed (n=9 [12.2%])
    Protocol noncompliance n=0
    Adverse event n=1
    Lack of efficacy n=2
    Request by subject n=3
    Lost to follow-up n=0
    Death n=1
    Other n=1
  Analysed (n=74)
    Completed (n=65 [87.8%])

Allocated to SC rilonacept + oral placebo (n=75) Treated (n=75)
  Withdrawed (n=11 [14.7%])
    Protocol noncompliance n=2
    Adverse event n=1
    Lack of efficacy n=2
    Request by subject n=2
    Lost to follow-up n=2
    Death n=0
    Other n=2
  Analysed (n=73)
    Completed (n=64 [85.3%])