

Enrolment

Assessed for Eligibility n = 236

Excluded n = 8
Not meeting inclusion criteria n = 8
Refused to participate n = 0
Other reasons n = 0

Randomised n = 228

Allocation

Allocated to high dose intervention n = 57
Received allocated intervention n = 57
Did not receive allocated intervention n = 0

Allocated to medium dose intervention n = 56
Received allocated intervention n = 55
Did not receive allocated intervention n = 1 (wrong pack)

Allocated to low dose intervention n = 58
Received allocated intervention n = 56
Did not receive allocated intervention n = 2 (ineligible, wrong pack)

Allocated to matching placebo n = 57
Received allocated intervention n = 57
Did not receive allocated intervention n = 0

Follow up

Lost to follow up n = 0
Discontinued trial n = 1 (allergy (1))

Lost to follow up n = 4 (withdrew consent (2) discharged (1) transfer (1))
Discontinued trial n = 1 (discharged (1))

Lost to follow up n = 3 (discharged(1), not known (2))
Discontinued trial n = 6 (ineligible (1), transfer (2), withdrew consent (2), Due to trial treatment suspension (1))

Lost to follow up n = 0
Discontinued trial n = 2 (transfer (1), due to trial treatment suspension (1))

Analysis

Analysed n = 57
Excluded from analysis n = 0

Analysed n = 52
Excluded from analysis n = 4 (withdrew consent (2) discharged (1) transfer (1))

Analysed n = 54
Excluded from analysis n = 4 (ineligible (1), discharged (1), not known (2))

Analysed n = 57
Excluded from analysis n = 0