

Assessed for eligibility
(n=79)

Excluded (n=19)

- Not meeting inclusion criteria (n=14)
- Declined to participate (n=5)
- Other reasons (n=0)

Randomised (n=60)

M72/AS01_E (n=40)

- Received allocated intervention (n=40)
- Did not receive allocated intervention (n=0)

Saline Placebo (n=20)

- Received allocated intervention (n=20)
- Did not receive allocated intervention (n=0)

- Loss to follow up (n=0)
- Discontinued intervention (n=0)

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- Discontinued intervention (n=0)

Safety Analysis

- Analysed (n=40)
- Excluded from analysis (n=0)

Safety Analysis

- Analysed (n=20)
- Excluded from analysis (n=0)

Immunogenicity Analysis

- Analysed according-to-protocol (n=39)
- Excluded (n=1)
 - Reason for exclusion: Non-compliance with blood sampling time windows

Immunogenicity Analysis

- Analysed according-to-protocol (n=20)
- Excluded (n=0)

Allocation

Follow-up

Analysis