Individuals assessed for eligibility (N)

Excluded \( X = X_1 + X_2 \)
- Not meeting inclusion criteria \( X_1 \)
- Declined to participate \( X_2 \)
- Other reasons \( X_3 \)

Randomized \( n=N-X \)

Allocation

Allocated to intervention IM * \( (n/2) \)
- Received allocated intervention \( (n_1) \)
- Did not receive allocated intervention (give reasons) \( (n/2-n_1) \)

Allocated to intervention SC ** \( (n/2) \)
- Received allocated intervention \( (n_2) \)
- Did not receive allocated intervention (give reasons) \( (n/2-n_2) \)

Follow-Up

Lost to follow-up (give reasons) \( (n_3) \)
Discontinued intervention (give reasons) \( (n_1-n_3) \)

Lost to follow-up (give reasons) \( (n_4) \)
Discontinued intervention (give reasons) \( (n_2-n_4) \)

Analysis

Analysed \( (n_5) \)
- Excluded from analysis (give reasons) \( (n_3-n_5) \)

Analysed \( (n_6) \)
- Excluded from analysis (give reasons) \( (n_4-n_6) \)

* IM: intramuscular injection
** SC: subcutaneous injections