

## Enrollment

Assessed for eligibility (n=281)

Excluded (n= 61)

- ◆ Not meeting inclusion criteria (n=29)
- ◆ Declined to participate (n=19)
- ◆ Other reasons (n=13)

Randomized (n=220)

## Allocation

Allocated to MTX alone (n=110)

Allocated to MTX+PDN (n=110)

## Follow-Up

Lost to follow-up (n=12)

Lost to follow-up (n=9)

## Analysis

Incomplete outcome (n=8)  
Analysed (n= 90)

Incomplete outcome (n=5)  
Analysed (n= 96)