Low-dose MTX for reduction of GINA Step 5 medications in Chronic Severe Asthma

Run-in  →  Active Treatment  →  Run-out

MTX

Placebo

Step 5 Medications:
- OCS dose reduction
- Omalizumab dose reduction

0 3 6 12 18 24 30  Week

Enrollment
Visit 0

Consent
Asthma Hx
Drug Hx
Physical exam
Vitals
Spiro
PROs
Lab routine
Total IgE
Skin test
Pregnancy
Liver US
Chest X ray

Randomize
Visit 1

Drug Hx
Vitals
Spiro
PROs
MTXPG assay
Pregnancy

Updosing
Visit 2

Drug Hx
Vitals
Spiro
PROs
Lab routine

Visit 3

Drug Hx
Vitals
Spiro
PROs
Lab routine

Visit 4

Drug Hx
Vitals
Spiro
PROs
Lab routine

Visit 5

Drug Hx
Vitals
Spiro
PROs
Lab routine

Visit 6

Drug Hx
Vitals
Spiro
PROs
Lab routine

Visit 7

Drug Hx
Vitals
Spiro
PROs
MTXPG assay

Visit 8

Drug Hx
Vitals
Spiro
PROs
MTXPG assay

AEs
Study Diary

0.75x  →  0.50x  →  0.25x  →  0.00x  →  OCS dose reduction

0.50x  →  0.00x  →  Omalizumab dose reduction