

Randomized Embedded Adaptive Platform Clinical Trial in South Asian Kidney Biopsy-Proven Primary Glomerular Diseases: Multi-center, Multi-arm and Multi-stage -India Alliance GRACE IgAN Platform Trial



18-65 years



Biopsy proven IgAN



UPCR ≥ 0.75 g/g



eGFR ≥ 20 ml/min /1.73 m²



Maximal RAAS inhibition for ≥ 3 months + Dapagliflozin 10 mg/day

Control – Maximally tolerated RAAS inhibition + Dapagliflozin 10 mg per day

Intervention 1:
Oral
Prednisolone
0.5mg/kg/day
for 2 months -
> 5 mg/month
tapering for 6-
9 months

Intervention 2:
Gut directed
Budesonide
12mg/day for 9
months ->
tapered by 3 mg
every 3 months
until 18 months

Intervention 3:
MMF 1.5g/day
for 12 months
followed by ->
1 g/day for 6
months

Intervention 4:
HCQs 6.5
mg/kg/day for
24 months

Intervention 5:
Non steroidal
mineralocortic
-oid antagonist
for 24 months

All interventions arms have baseline maximally tolerated RAAS inhibition + Dapagliflozin

Primary Outcome: Mean change in annualised eGFR slope at 24 months

Secondary Outcome: Mean change in UPCR, Proportion of individuals reaching composite end points