MAINRITSAN 3

MAINTENANCE OF REMISSION USING RITUXIMAB IN SYSTEMIC ANCA-ASSOCIATED VASCULITIS (AAV)

EXTENDED MAINTENANCE THERAPY LEADS TO BETTER CLINICAL OUTCOMES[1,2]

- Relapse rates were reduced in patients receiving long-term RTX treatment compared to standard maintenance therapy
- With standard maintenance therapy relapse rates remain high, at month 28 25% of patients experienced a relapse
- There was no difference in the incidence of AEs with long-term treatment

VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA

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INTRODUCTION

MAINRITSAN 3 assessed the efficacy of extended maintenance therapy with RTX to prevent the occurrence of relapses.[1] Previous studies have demonstrated RTX to be an effective maintenance therapy, however relapses remain common following RTX discontinuation.[1,2]

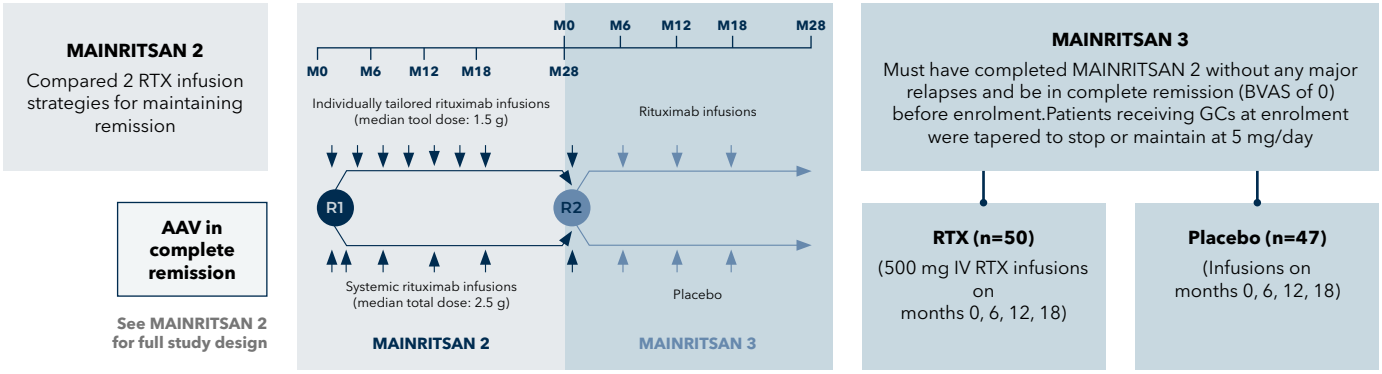
STUDY AIM

Evaluate the efficacy of prolonged RTX use in maintaining remission in AAV patients who achieved full remission after an 18-month maintenance regimen vs placebo.[1]

The sponsor of this study was:
Assistance Publique – Hôpitaux de Paris

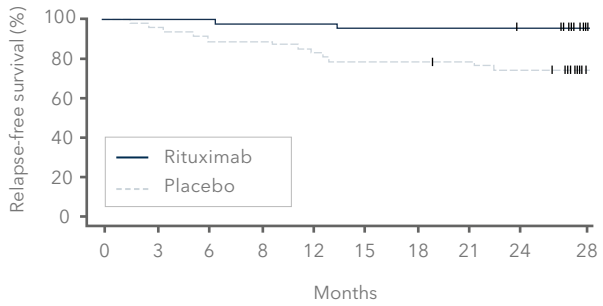
STUDY DESIGN

Randomised, double-blind, multicentre trial[1]



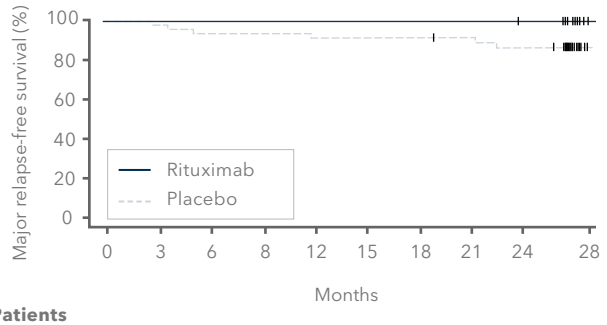
RESULTS

At month 28 relapse-free survival was lower in the RTX group compared to the standard maintenance therapy plus placebo, 96% vs 74%, an absolute difference of 22% ($p<0.05$). Major relapse-free survival was significantly lower in the RTX group vs the placebo group, 100% vs 87% ($p<0.01$), minor relapse was also lower in the RTX group 96% vs 87%. No difference was observed in the incidence of AEs, serious infections and VDI scores between groups.[1]



Patients at risk, n

Rituximab	50	50	50	49	49	48	48	48	47	32
Placebo	47	45	43	42	40	37	37	36	34	21



Patients at risk, n

Rituximab	50	50	50	50	50	50	50	50	49	33
Placebo	47	46	44	44	44	43	43	42	40	24

CONCLUSION

Prolonging the use of RTX treatment for an additional 18 months was effective in maintaining remission. The use of RTX long-term did not raise any additional safety concerns.

In summary, extended RTX therapy with 6-monthly infusions over 18 months was associated with a lower relapse rate than standard maintenance therapy.[1]

REPEATED RTX 500 MG IV EVERY 6 MONTHS OVER 18 MONTHS WAS EFFECTIVE IN SUSTAINING REMISSION VS AZA

References & footnotes

AAV, ANCA-associated vasculitis; AEs, adverse events; ANCA, anti-neutrophil cytoplasmic antibody; AZA, azathioprine; BVAS, Birmingham Vasculitis Activity Score; GC, glucocorticoid; M, month; MPO, myeloperoxidase; PR3, proteinase 3; R, randomisation; RTX, rituximab; VDI, Vasculitis Damage Index

*To be included in the study patients must have successfully completed MAINRITSAN 2 without any major relapses and me in complete, patients were assigned to the receive the RTX regimen (500 mg IV on months 0, 6, 12 and 18; GPA: 64%, MPA: 36%; mean age: 64.6; male: 70%) or placebo (GPA: 77%, MPA: 23%; mean age: 63.1; male: 76%) between March 2015 and April 2016. Relapse defined as reappearance or worsening of AAV, that is BVAS >0. Major relapse defined as life threatening or involving at least 1 major organ. Minor relapse defined as reappearance or worsening of AAV with BVAS >0, not corresponding to a major relapse.[1]

1. Charles P, et al. *Ann Intern Med* 2020;173(30:179–87.
2. Terrier B, et al. *Ann Rheum Dis* 2018;77(8):1150–6.