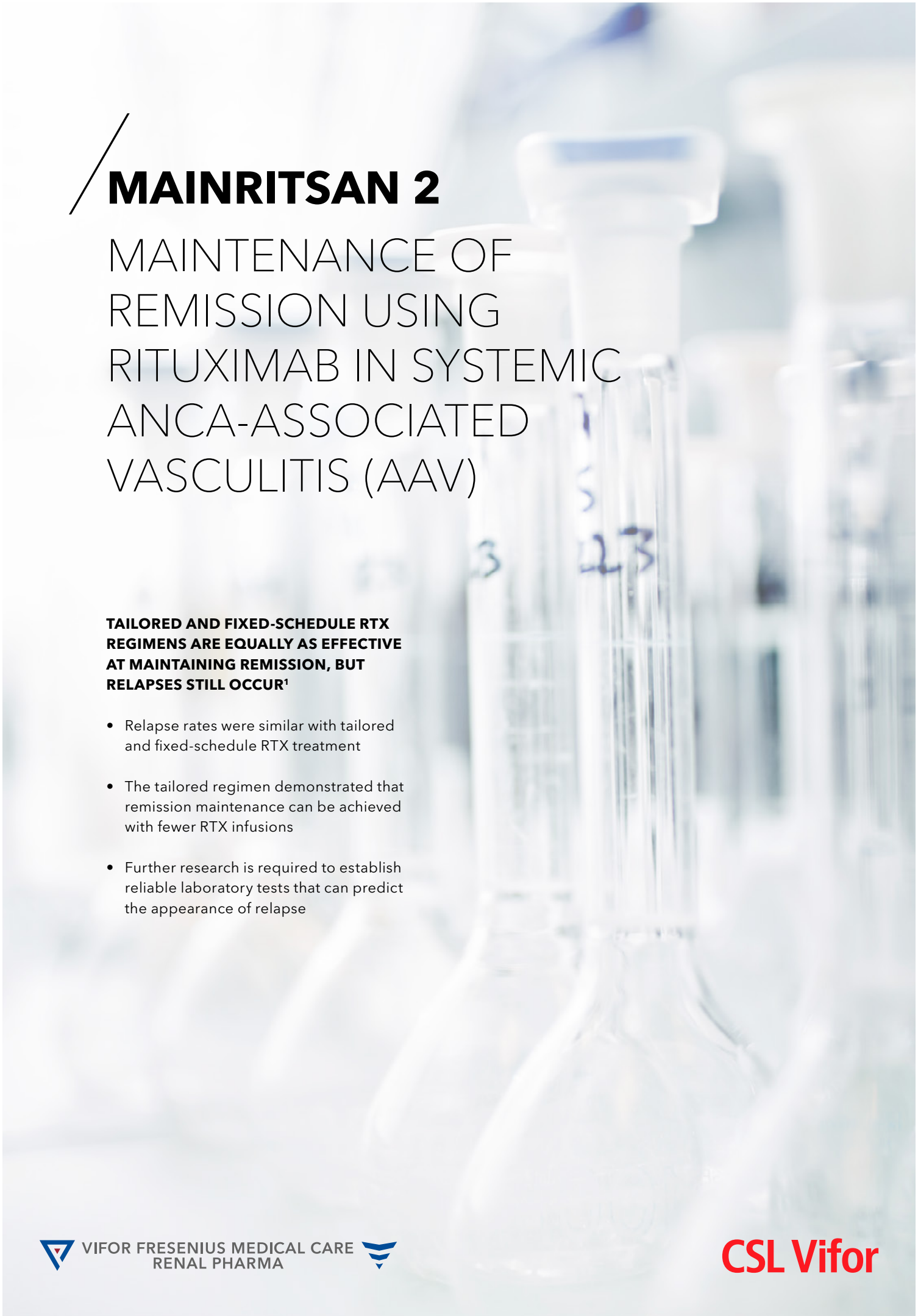


MAINRITSAN 2

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

TAILORED AND FIXED-SCHEDULE RTX REGIMENS ARE EQUALLY AS EFFECTIVE AT MAINTAINING REMISSION, BUT RELAPSES STILL OCCUR[1]

- Relapse rates were similar with tailored and fixed-schedule RTX treatment
- The tailored regimen demonstrated that remission maintenance can be achieved with fewer RTX infusions
- Further research is required to establish reliable laboratory tests that can predict the appearance of relapse

VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA

CSL Vifor

INTRODUCTION

MAINRITSAN 2 evaluated the use of ANCA and B cells as indicators for the onset of relapse by comparing a tailored RTX regimen (RTX was administered based on changes to the indicators), with a fixed-schedule RTX. Evidence exists that the reappearance of ANCA and increases in ANCA titres and circulating B cell levels may be associated with relapses and can be used to predict their onset, but this remains controversial.

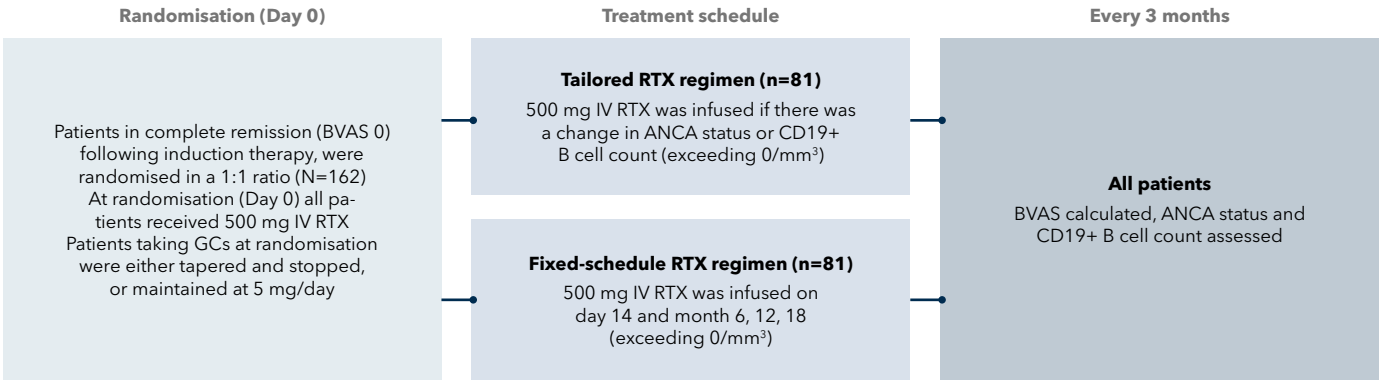
STUDY AIM

Compare individually tailored RTX treatment (based on ANCA-positivity/titre change and/or circulating CD19+ B cells) with a fixed-schedule RTX regimen to maintain remission.

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

STUDY DESIGN

Randomised, open-label, multicentre, control study

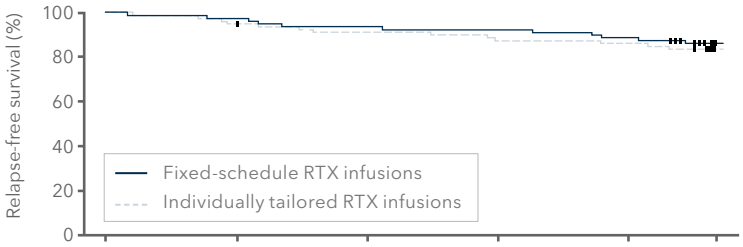


PRIMARY ENDPOINT

Number of relapses at month 28, defined as the reappearance or worsening of AAV (BVAS >0)

RESULTS

At month 28 relapses rates did not differ significantly between the tailored and fixed-schedule RTX treatment, 17% vs 10%, and relapse-free survival rates were similar, 84% vs 86%. The total number of RTX infusions were lower in the tailored group compared to the fixed-schedule group, 248 vs 381, with the incidence of AEs similar amongst the two groups.



No. at risk						
Fixed-schedule	81	79	76	75	72	59
Individually tailored	81	77	73	70	69	59

CONCLUSION

Relapse rates occurred slightly more frequently in the tailored regimen but this difference was non-significant, indicating that it is possible to maintain remission with fewer RTX infusions. The study found ANCA and B cells were not reliable measures to predict relapses, but they did reduce the number of infusions that patients received without a significant increase in relapse rates.

In summary, relapse rates were similar between the RTX treatment regimens and a more personalised approach to treatment could reduce the total dose of treatment patients receive.

RELAPSE RATES WERE SIMILAR WITH TAILORED AND FIXED-SCHEDULE RTX TREATMENT

References & footnotes

AAV, ANCA-associated vasculitis; AEs, adverse events; ANCA, anti-neutrophil cytoplasmic antibody; BVAS, Birmingham Vasculitis Activity Score; ELISA, enzyme-linked immunosorbent assay; GC, glucocorticoid; GPA, granulomatosis with polyangiitis; IV, intravenous; MPA, microscopic polyangiitis; MPO, myeloperoxidase; PR3, proteinase 3; RTX, rituximab

*Patients with newly diagnosed or relapsing AAV in complete remission after induction treatment were enrolled between November 2012–13 and randomised to receive tailored RTX treatment (GPA: 69%; MPA: 31%; mean age: 62 years; male: 62%) or fixed-schedule RTX (GPA: 75%; MPA: 25%; mean age: 59 years; male: 54%). Patients were followed every 3 months up to 28 months. Change in ANCA status defined as; reappearance after being negative, indirect immunofluorescence-determined ≥2-dilution-titre increase and/or at least doubled ELISA PR3 or MPO.

Charles P, et al. *Ann Rheum Dis* 2020;173(30):1143–9.