Rituximab compared to intravenous cyclophosphamide in adults with connective tissue disease-associated interstitial lung disease: the RECITAL RCT

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Plain language summary

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Interstitial lung disease, a condition characterised by inflammation and scarring of the lungs, is the leading cause of death in systemic sclerosis (an autoimmune disease that typically causes thickening and scarring of the skin and which is associated with internal organ problems such as interstitial lung disease and kidney failure), and a major cause of morbidity (illness) in many other connective tissue diseases; a group of conditions that are caused by over activity of the immune system.

When interstitial lung disease associated with connective tissue disease gets worse over time, treatment such as intravenous cyclophosphamide is required to slow down lung scarring. Occasionally, standard immunosuppressive drugs fail to control lung inflammation and scaring and this can result in death.

Rituximab, a novel therapy, has been proven to be of benefit in suppressing inflammation associated with immune system over activity. Observational studies suggest that rituximab may be an effective treatment for pulmonary inflammation in connective tissue diseases.

The study was designed to determine how well rituximab works compared to cyclophosphamide in treating patients with severe connective tissue disease-associated interstitial lung disease. We recruited 101 participants from 11 hospitals throughout the UK who were randomly allocated to one of two groups. Those in the first group were given rituximab on day 1 of the study and then on day 14. They were then given a placebo every 4 weeks for the next 18 weeks. Those in the second group were given cyclophosphamide every 4 weeks from day 1 of the study to week 20. On day 14, they were given a placebo. Lung function for all participants was assessed at 24 weeks.

Our results suggest that rituximab improved lung function and quality of life but was not better than cyclophosphamide. Rituximab was associated with fewer unexpected medical events and a trend towards reduction in corticosteroid use and should be considered as a therapeutic alternative to cyclophosphamide.

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