A randomised clinical trial of a novel pharmacist-led glucocorticoid tapering intervention

Overview

Glucocorticoids (GCs, also known as steroids or prednisone/prednisolone) are frequently used in the treatment of many autoimmune inflammatory rheumatic diseases (AIRDs), including Rheumatoid Arthritis (RA), Polymyalgia Rheumatica (PMR) and Giant Cell Arteritis (GCA). While they can relieve symptoms, they are also associated with many side effects including reduced life expectancy, infection, weight gain, hypertension, diabetes, osteoporosis, cataracts, mood disturbance, thin skin, and easy bruising. In recognition of this, Australian Living Guidelines for RA recommend against the long-term use of GCs. However, studies have shown that once GCs are started, they are often difficult to stop, even when the joint disease of RA appears to be well-controlled. Reducing and stopping GCs is often difficult to achieve in the clinic setting, where there are often insufficient resources to provide comprehensive education and support. Currently, there are no proven interventions or guidelines for improving GC tapering and cessation in patients with AIRDS. However, the impact of GC-related adverse effects on patients is significant and improved tapering and cessation of these drugs will likely lead to an improvement in both physician-measured and patient reported outcomes. This study aims to develop a pharmacist-led intervention to support GC reduction and cessation, helping minimise associated side effects in AIRD patients, compared to usual care.

Lay Summary

This study aims to test the effectiveness and patient satisfaction of a pharmacist-led program to help patients with inflammatory diseases, such as Rheumatoid Arthritis (RA), Polymyalgia Rheumatica (PMR) and Giant Cell Arteritis (GCA), to reduce or stop taking glucocorticoids (GCs) over six months.

The study involved patients from two rheumatology clinics who were already using glucocorticoids and needed to lower or stop their dose as part of their regular treatment. Patients were randomly assigned to either a "control" group, which only received standard care from their rheumatologist, or an "intervention" group, which received extra support from the intervention pharmacist. This pharmacist helped patients reduce their glucocorticoid doses gradually by providing regular, 4-weekly, check-ins (either by phone or in-person) to track progress, offer advice, and address any issues such as side effects or flare-ups of their condition. Patients in both groups had their progress measured over six months, and their experience with care was recorded.

So far, 90 patients have enrolled in the study, with 53 completing the 6-month trial. Among those who have finished the study, 14 out of 24 (58%) in the intervention group and 21 out of 29 (72%) in the control group successfully tapered their GCs to the target dose set by their rheumatologist at the start of the study**.** All intervention group participants who did not meet their 6-month GC target dose were due to flares/relapses and 75% of those in the control group were similarly due to a relapse/flare of

their condition. The study is expected to conclude in July 2025, after which the results will be analysed and shared.

The goal of this research is to see whether the pharmacist-led approach helps patients reduce their glucocorticoid doses safely and whether it improves their overall care experience.