Secukinumab in Behçet’s: Lay summary

Background: This study investigated the potential for new treatment, Secukinumab, to be used for patients diagnosed with non-ocular Behçet's Syndrome.

Methods: This was a phase II, proof of principle trial set up to evaluate potential for safety and efficacy of in this group of patients. The patient population studied had previously not responded to first line therapy with topical steroid (mouth wash or skin cream), colchicine or azathioprine. A total of 64 patients recruited had been calculated to produce a significant result.

Patients were randomly assigned to either the placebo or the study drug (secukinumab) arm. Each patient receiving either 300mg subcutaneous (under the skin) injection of Secukinumab or matched placebo up to week 16. Injections were self-administered once a week for four weeks (weeks 0, 1, 2, 3, 4), then once every four weeks at week 8 and 12. From week 16 all patients received active drug, 300mg Secukinumab, every 4 weeks up to and including week 48. Patients were required to attend 6 scheduled clinic visits and had 6 follow-up telephone calls. The total duration of each patient's time in the study was approximately 1 year. The primary outcome was change in oral ulcer severity score (USS). Secondary outcomes included changes in activity in other organ systems, patient-reported outcomes and potential to reduce co-existent steroids.

Results: 64 patients were recruited (33 randomised to secukinumab and 31 to placebo). the predefined primary endpoint (improvement in oral USS) and most of the secondary endpoints were not met, with the exception of significant benefits in patient global score and in ability to reduce the dose of steroids in patients randomised to secukinumab. There were no identified safety issues with respect to AE’s SAE’s, and TEAEs, with a similar spectrum of events between both groups and no new safety signals identified in patients taking 36 weeks of secukinumab after the 16weeks of randomisation.

Conclusion: In this phase II randomised trial comparing secukinumab with placebo there was no significant improvement in the primary outcome (oral USS) and most other secondary outcomes. However, there were significant improvements in patient’s global assessment and in the ability to reduce dose of concomitant steroid. This trial suggests a potential beneficial effect of secukinumab in non-ocular Behçet’s, but further work is required to clarify this and identify if the effect is limited to subgroups of disease.