

Analysis of data collected from clinic reproduced psoriasis drug trial results

December 10 2020, by Mike Addelman

The difference in effect of two drugs commonly used to treat psoriasis was reliably reproduced from a clinical trial by a large observational study carried out by University of Manchester and Salford Royal NHS Foundation Trust scientists. The study from the British Association of Dermatologists Biologics and Immunomodulator Register (BADBIR) compared the effectiveness of secukinumab against ustekinumab, two biologics used to treat the common chronic inflammatory skin condition psoriasis.

The research was supported by the NIHR Manchester Biomedical Research Centre (BRC). Manchester BRC bridges the gap between new discoveries and individualised care through pioneering research. The BRC's Dermatology theme is using a precision medicine approach to prevent and predict [disease progression](#) and personalise treatment pathways for inflammatory skin disease and chronic wounds.

Published in *JAMA Dermatology* and funded by the NIHR and the British Association of Dermatologists, they found the relative treatment effect was robust when benchmarked against a clinical trial of the two biologic drugs.

An observational study passively monitors people receiving treatment rather than actively intervening and designating people to certain treatments as in [clinical trials](#). Secukinumab was approved in 2015 in the United States and European Union to treat adults with moderate-to-severe [psoriasis](#), as was ustekinumab in 2009.

The study team used real world data from BADBIR, which from 2007 has been collecting data from volunteers in the UK and Ireland who are using biologic and other therapies to treat their psoriasis. BADBIR was set up to see if there are any differences in the safety profile between biologic therapies and the more established psoriasis treatments.

Lead author Dr. Zenas Yiu is a NIHR Clinical Lecturer in Dermatology at the University of Manchester and Specialty Registrar in Dermatology at Salford Royal NHS Foundation Trust. He said: "We know that randomised clinical trials can over-estimate the effect of medicines when compared with what happens to the population of patients suffering from the condition outside of trials. However, it is not yet clear whether observational studies can robustly test the relative effectiveness between two different psoriasis treatments. We wanted to see how effective secukinumab and ustekinumab were for the treatment of psoriasis in a large population of patients with psoriasis outside the trial setting in the U.K. We also wanted to and see if we can reach the same conclusions as the equivalent published clinical trial as to which treatment was more effective."

The team observed if patients had a Psoriasis Area and Severity Index score, the most commonly used disease severity score for psoriasis, of 2 or lower after 12 months of either treatment. They compared the results to an international trial called the CLEAR trial, which compared secukinumab to ustekinumab.

The results of the study showed that, as expected, the treatment effect for both secukinumab and ustekinumab were approximately 15% lower in BADBIR compared with the CLEAR trial. However, the relative effect in BADBIR between the two treatments was similar to CLEAR, with a relative risk of achieving the outcome for secukinumab compared with ustekinumab of 1.28 in BADBIR compared with 1.24 in CLEAR.

He added: "We feel these results important as they confirm that less patients respond to secukinumab and ustekinumab in the real-world compared with the strictly selected and monitored clinical trial environment. Despite these differences, we replicated the relative treatment effect between [secukinumab](#) and [ustekinumab](#) found in the CLEAR trial reliably in BADBIR. Although data from randomised controlled [trials](#) remain the gold-standard evidence for evaluation of treatment efficacy, our study suggests that, with the right analytical approach, observational data can also be used to inform clinical treatment decision making. We feel that in the future, data from BADBIR may reliably tell us about the relative effect of other treatments for psoriasis that are currently not informed by trial evidence."

More information: Zenas Z. N. Yiu et al. Randomized Trial Replication Using Observational Data for Comparative Effectiveness of Secukinumab and Ustekinumab in Psoriasis, *JAMA Dermatology* (2020). [DOI: 10.1001/jamadermatol.2020.4202](https://doi.org/10.1001/jamadermatol.2020.4202)

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