Baseline characteristics of the BeNeBio cohort: Dose Reduction of the New Generation Biologics (IL-17 and IL-23 Inhibitors) in Psoriasis: a Pragmatic, Multicentre, Randomized, Controlled, Non-inferiority Study

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Background:
Psoriasis is a chronic inflammatory skin disease for which treatment with biologics is highly effective. Tightly controlled dose reduction (DR) of the first-generation biologics has proven to be efficient and cost-effective. The present study evaluates whether controlled DR of IL-17 and IL-23 inhibitors in psoriasis patients with low disease activity is non-inferior to usual care (UC).

Materials and Methods:
244 patients using IL-17 or IL23 inhibitors on standard dose with low disease activity (Psoriasis Area and Severity Index (PASI) ≤ 5 for at least 6 months), and PASI and Dermatology Life Quality Index (DLQI) ≤5 at time of inclusion, are randomized (2:1) to DR or UC. With DR, dosing intervals are stepwise prolonged to achieve 66% and 50% of the original dose. In case of disease flare, treatment is adjusted to the previous effective dose. Primary outcome is the difference in cumulative incidence of persistent flares (PASI >5 for ≥3 months). Secondary outcomes include proportion of patients with successful DR, (course of) PASI and DLQI, serious adverse events, health related quality of life, costs, and pharmacokinetic profile.

Results:
In September 2023, 100% inclusion was reached: 14% used secukinumab, 25% ixekizumab, 6% brodalumab, 1% bimekizumab, 30% guselkumab, 21% risankizumab, and 2% tildrakizumab. Of included patients, mean age is 50 years, mean BMI is 27.4, and 67% is male. Of all patients, 14% has psoriatic arthritis. Median disease duration at inclusion is 21 years (IQR 20). Previously used treatments involves topical corticosteroids (86%) and topical vitamin D derivates (36%), UV-light therapy (84%), MTX (86%), ciclosporin (49%) and at least one biological treatment (50%). At baseline, median PASI is 0.0 (IQR 1.1) and DLQI is 0.0 (IQR 1.0).

Conclusions:
Although the threshold for inclusion was PASI and DLQI ≤5, patients have been included with a very low PASI and DLQI (both median 0). Additionally, patients show a relatively low mean BMI compared to general biologic cohorts, and the proportion of biologic naive vs. non-naive patients is well balanced. In clinically stable patients, DR may lead to more efficient and rational use of biologics.

Key words (max. 6): Psoriasis – Dose reduction – biologicals – Pharmacokinetics

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