

Number: 2SPD-035

ATC code: L04 - Immunosuppressive agents

Background

The current treatment of psoriasis aims to achieve maintained control of skin involvement and systemic inflammation, as well as the prevention of the onset or progression of systemic comorbidities and depends on the severity of the disease.



Purpose

→ The objective was to perform a comparative of the most common therapies in the treatment of patients with moderate to severe psoriasis used as an alternative to tumour necrosis factor-alpha inhibitors (anti-TNFα)



Material and methods

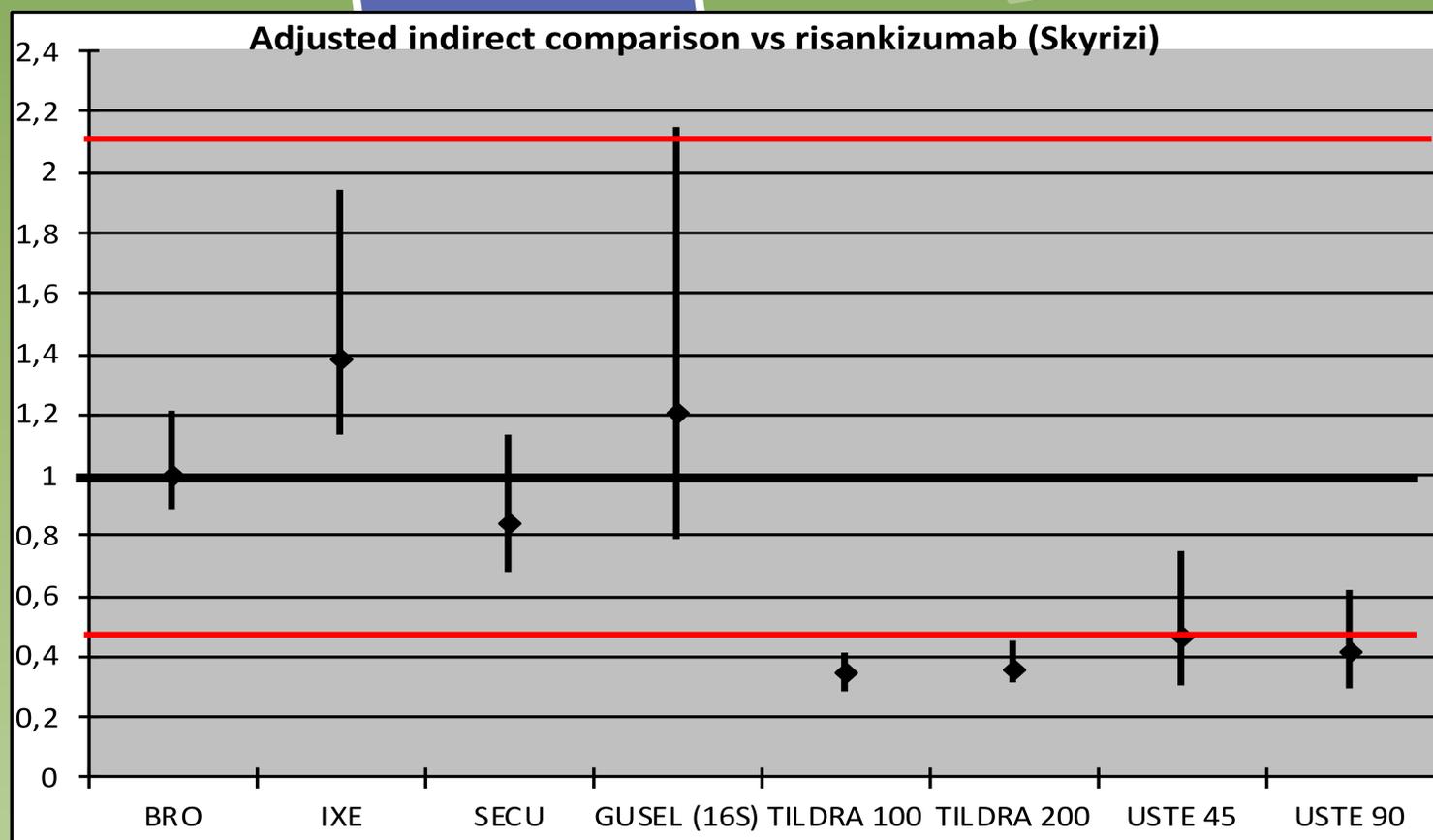
The therapies included were found after a systematic search performed in Pubmed. The analysis included randomized, double-blind, phase 3, controlled trials, non-TNF-targeted therapies and PASI75 measurement after 12-16 weeks of treatment. The analysis was performed using the R® software to estimate Bayesian statistics, with risankizumab taken as a reference for the comparison.

A delta value of 14%, as provided by the regulatory agencies FDA and EMA, was used to determine the maximum acceptable difference as a non-inferiority criteria) and the average PASI75 response was set at 79% (IC95: 74-84) (ULTIMMA1 and ULTIMA2 trials). To establish the therapeutic positioning, the ATE (Equivalent Therapeutic Alternatives in Spanish) Guide criteria were applied.



Results

Figure 1. An equivalence margin expressed as Odd Ratio (OR) was established from 0.46 to 2.11. The results of the different treatment against risankizumab (reference) expressed as OR (IC95%) were: 1.89-1.21 [Brodalumab], 1.39 (1,13-1,94) [Ixezumab], 0.84 (0,0.68-1.13) [Secukinumab], 1.21 (0.79-2.15) [Guselkumab], 0.35 (0.28-0.41) [Tildrakizumab], 0.47 (0.3-0.75) [Ustekinumab].



Conclusions

Brodalumab and secukinumab are identified as risankizumab equivalent. With regard to ixekizumab, it can be considered as a clinical equivalent, even though statistically significant differences (ixekizumab vs risankizumab) are observed but are clinically irrelevant.

In the case of guselkumab, it can be labelled as a possible clinical equivalent as IC95 exceeds the equivalence margin, but it is not sure that such a difference exists (being statistically non-significant).

Ustekinumab and tildrakizumab cannot be considered equivalent, the former had likely relevant and statistically significant differences (being the 50% of its IC95 outside the equivalence range), and tildrakizumab had clearly relevant and statistically significant differences as all of its IC95s were outside the equivalence range.