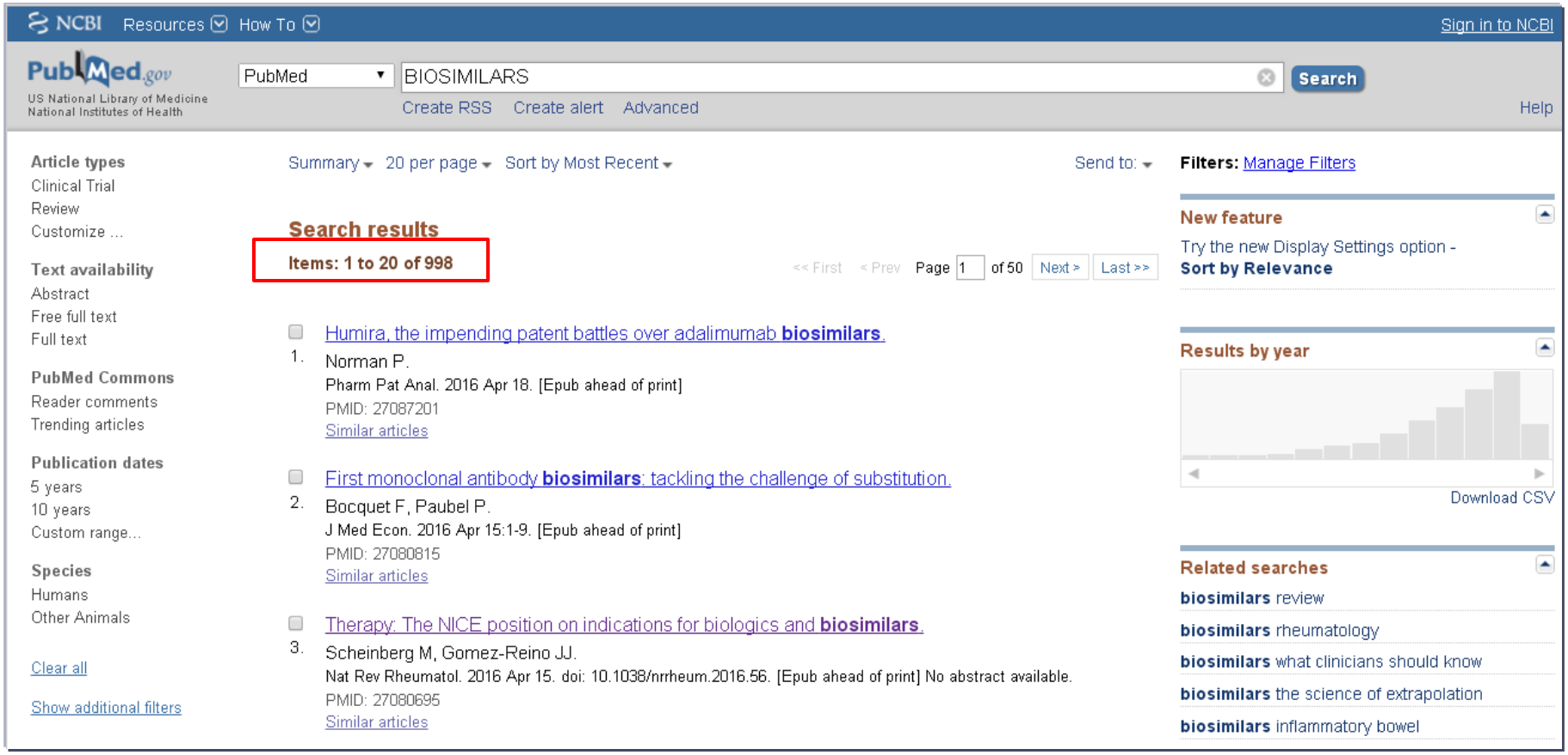
Ο ρόλος των αντι-TNF στη Ρευματολογία: Η εισαγωγή των βιο-ομοειδών

Ορισμός

Βιο-ομοειδές: είναι ένα βιολογικό φαρμακευτικό προϊόν, το οποίο είναι παρόμοιο ως προς την ποιότητα, ασφάλεια και αποτελεσματικότητα με το βιολογικό προϊόν αναφοράς (ένας ήδη εγκεκριμένος βιολογικός παράγοντας)

Βιο-ομοειδή (Bio-similars)

- 2004: Πρώτη αναφορά στα "biosimilars" στο Pubmed
- 2011: 16 βιο-ομοειδή στην αγορά
- 19-04-2016: 998 αναφορές στο PubMed



The changing landscape of biosimilars in rheumatology

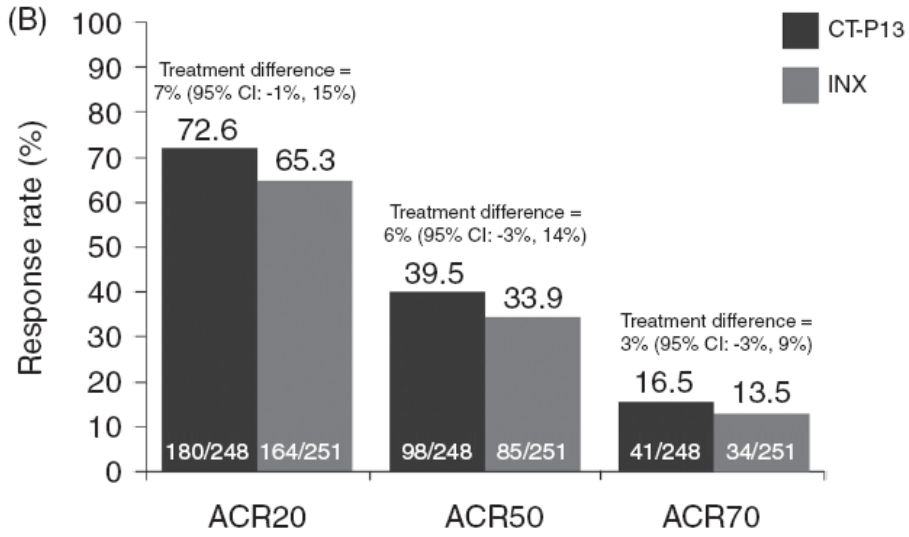
Thomas Dörner, Vibeke Strand, Paul Cornes, João Gonçalves, László Gulácsi, Jonathan Kay, Tore K Kvien, Josef Smolen, Yoshiya Tanaka and Gerd R Burmester

Ann Rheum Dis published online March 8, 2016

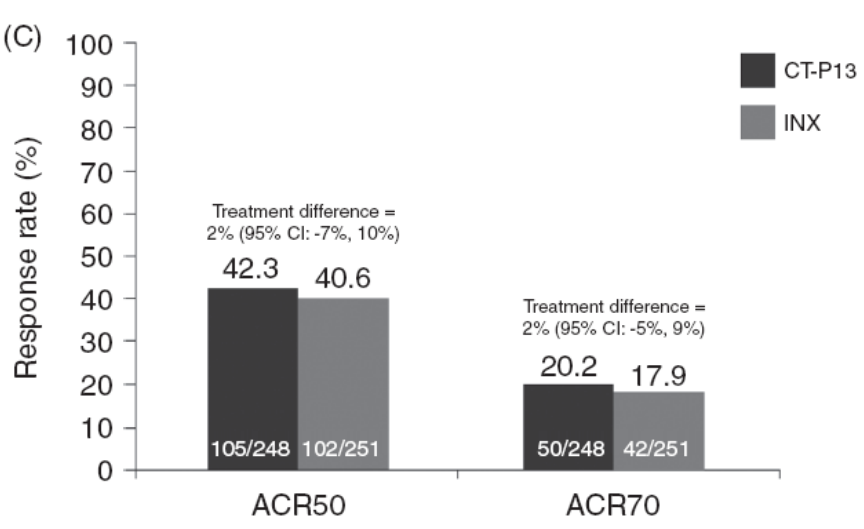
PLANETRA study: CT-P13 vs Infliximab

Αποτελεσματικότητα

Week 14

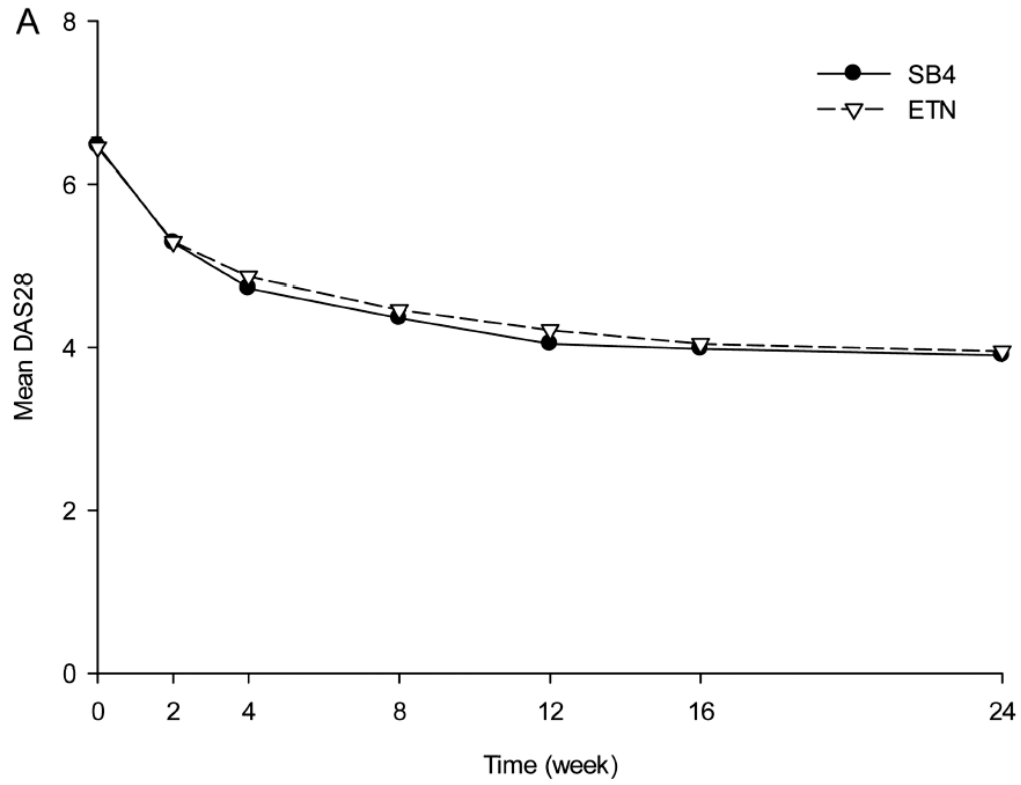


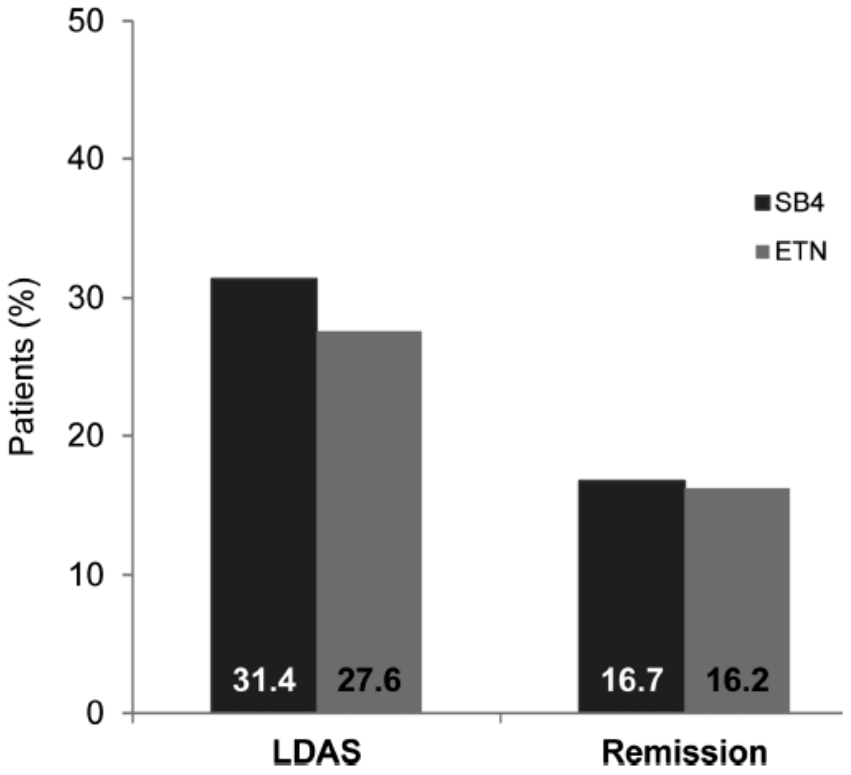
Week 30



Yoo DH et al. Ann Rheum Dis 2013

A phase III randomised, double-blind, parallel-group study comparing SB4 with etanercept reference product in patients with active rheumatoid arthritis despite methotrexate therapy





Emery P et al. Ann Rheum Dis 2015

EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013 update

Josef S Smolen, Robert Landewé, Ferdinand C Breedveld, et al.

9. *In patients responding insufficiently to MTX and/or other csDMARD strategies, with or without glucocorticoids, bDMARDs (TNF inhibitors, abatacept or tocilizumab, and, under certain circumstances, rituximab) should be commenced with MTX.* This point was approved as worded by

> and overall safety.[110] Therefore the Task Force decided by a 90% majority vote that no preference of one over another biological agent should be expressed in the 2013 update of the recommendations. However, the Task Force recognised that there was still more experience with TNF inhibitors than with other bDMARDs, and that more safety data from registries would be desirable for the newer bDMARDs.

biological agent at present. Fourth, when speaking of TNF inhibitors, the Task Force listed the presently approved agents, adalimumab, certolizumab pegol, etanercept, golimumab and infliximab, but also decided to mention biosimilars under the proviso that they become approved in the USA and/or Europe; current data suggest that at least one biosimilar, CT-P13, has a similar efficacy and safety profile

Smolen JS et al. Ann Rheum Dis 2013

EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013 update

Josef S Smolen, Robert Landewé, Ferdinand C Breedveld, et al.

10. *If a first bDMARD has failed, patients should be treated with another bDMARD; if a first TNF inhibitor therapy has failed, patients may receive another TNF inhibitor or a biological agent with another mode of action.* A consequence of item 9, recommendation 10 simply states that once the treatment target has not been reached with an initial biological therapy, other bDMARDs should be used; no preference is stated. The second part of this recommendation focusing on patients who have initially received a TNF inhibitor may seem somewhat redundant. However, it has two purposes: (i) to express the conclusion of the Task Force that current evidence does not suggest any one agent to be better than another TNF inhibitor when active disease prevails despite initial treatment with a TNF blocker; (ii) over the next few years, new biological agents targeting the IL-6 receptor (sarilumab) or IL-6 (clazakizumab, sirukumab) may become available[131–133]; without specific note on the options after failure of an initial TNF inhibitor therapy, one could infer that potentially approved new IL-6 inhibitors might be used after failure of tocilizumab, but in contrast with TNF inhibition, the efficacy of such an approach is currently unknown for IL-6 inhibition (or costimulation blockers or rituximab). Of note, with biosimilars approaching, it is self-evident that an infliximab biosimilar cannot be regarded as 'another TNF inhibitor' in patients with an insufficient response to infliximab. This recommendation was voted for by 97% of the members.

Smolen JS et al. Ann Rheum Dis 2013

Ερωτήματα-Προβληματισμοί

- Αυτόματη υποκατάσταση
- Ανταλλαξιμότητα
- Ανοσογονικότητα
- Ασφάλεια
- Registries-Φαρμακοεπαγρύπνηση