

Targeted Immune Modulators

Key Questions and Inclusion Criteria

Update #2

Key Questions

1. How do included drugs compare in their efficacy and long-term effectiveness for alleviating symptoms and stabilizing the disease in patients with rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, Crohn's disease, ulcerative colitis, or plaque psoriasis?
2. What are the comparative incidence and severity of adverse events associated with the use of these drugs?
3. Do the included drugs differ in effectiveness or adverse events in the following subgroups:
 - Different racial groups, genders, or age groups?
 - Patients taking other commonly prescribed drugs?

Inclusion criteria

Population

- Adult patients with moderately to severe rheumatoid arthritis
- Adult patients with ankylosing spondylitis
- Adult patients with psoriatic arthritis
- Adult patients with Crohn's disease
- Adult patients with ulcerative colitis
- Adult patients with plaque psoriasis
- Pediatric patients with juvenile idiopathic arthritis
- Pediatric patients with psoriatic arthritis
- Pediatric patients with Crohn's disease
- Pediatric patients with ulcerative colitis
- Pediatric patients with plaque psoriasis

Interventions

Anti TNF

- Adalimumab (Humira[®])
- Etanercept (Enbrel[®])
- Certolizumab (Cimzia[®])*

- Infliximab (Remicade[®])
- Interleukin-1 Receptor antagonist
- Anakinra (Kineret[®])
- Anti-CD11a
- Efalizumab (Raptiva[®])
 - Alefacept (Amevive[®])
- Cytotoxic T lymphocyte antigen immunoglobulin (CTLA 4-Ig)
- Abatacept (Orencia[®])
- Anti – CD 20a
- Rituximab (Rituxan[®])
- Anti - IgG4
- Natalizumab (Tysabri[®])

Effectiveness outcomes

All Health outcomes, e.g.:

- Quality of Life
- Functional capacity
- Employability, productivity
- Clinical improvement (e.g. ACR, DAS, BASFI, PASI)
- Disease remission
- Pain
- Reduction in the number of swollen or tender joints
- Hospitalizations
- Mortality
- Rebound
- Steroid withdrawal
- Avoidance of surgery

Safety outcomes

- Overall adverse events
- Withdrawals due to adverse events
- Serious adverse events reported
- Specific adverse events (e.g. lymphoma, serious infectious diseases, congestive heart failure)

Study design

- For effectiveness, controlled clinical trials, controlled prospective cohort studies, and good quality systematic reviews
- For safety, in addition to controlled clinical trials, observational studies will be included.

* Not available in Canada