

## **Objective**

This study addresses the question pertaining to patients, intervention, comparator, outcome (PICO) : In adults of more than 16 years of age with Crohn's disease or ulcerative colitis (P), do those who receive biologic drugs or placebo when having short-term duration of disease less than or equal to 18 months (I) compared to patients who have long-duration (<18 months) of disease (C), have higher rate of induction of remission by the biologic drug compared to placebo (O) ?

## **Methods used**

This is a systematic review and meta-analysis performed according to the Cochrane Handbook for Systematic Reviews of Intervention and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. Studies were identified by a search of the non-language restricted medical literature conducted with MEDLINE (1976 to November 2015) and EMBASE/EMBASE classic (1946 to November 2015). This was further supplemented by a search of the Cochrane CENTRAL register of controlled trials, the Cochrane IBD Group Specialized Trials Register, and clinical trials registry (Clinicaltrials.gov) using all developmental and generic drug names, as specified in supplementary material. Abstract proceedings from Digestive Diseases Week, United European Gastroenterology Week, and the European Crohn's and Colitis Organization between 2007 and November 2015 were hand-searched to identify potentially eligible studies published only in abstract form. Data will be pooled using a random effects model, which is preferred based on clinical heterogeneity across trials and assumed to provide a more conservative estimate of the likelihood of benefit of biologics in short-term disease. To performing meta-analyses of sub-group treatment effects and reducing across-trial confounding, coefficient for the treatment-by-subgroup interaction within each trial will be

computed as log odds ratio for the outcome for biologics versus placebo in patients with short disease duration compared to those with long duration of disease.

Remission is defined as per trial-specific time-point for induction outcome assessment, within our pre-specified range (week 4-14). The outcome will be expressed as combined (log) odds ratio of the coefficients computed separately for each individual study, for the odds ratio of short-term disease patients to respond to biologic compared to the long-disease duration patients in each trial.

## **Results**

We did not finish the data analysis, however we cleaned the data, defined all study variables necessary for the analysis and standardized the working parameters across the studies. We closely followed the protocol of the meta-analysis.

## **Conclusions**

No conclusions have been reached so far, prior to the actual meta-analysis to be conducted on all the available trials pooled together on the Vivli platform.