STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

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|  | Item No | Recommendation | Page No / Relevant text from manuscript |
| **Title and abstract** | 1 | (*a*) Indicate the study’s design with a commonly used term in the title or the abstract | Page 1;Observational, prospective, multicenter study in IBD patients treated with CT-P13 in clinical practice who were naïve to biological treatments, or fail to respond to other anti-TNF drugs, or had switched from infliximab.  |
| (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found | Page 1 (lines 49-87); Abstract |
| Introduction |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | Pages 5-6 (lines 99-146) |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | Page 6 (lines 144-146); In this study, we aimed to analyze clinical response rates to CT-P13, commercialized under the trade name of Remsima®, and adverse events in patients with IBD treated in real-life practice. |
| Methods |
| Study design | 4 | Present key elements of study design early in the paper | Pages 6-7 (lines 147-159); This was an observational, prospective, multicenter study conducted at eight Spanish hospitals.  |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | Page 6 (lines 160-176); The duration of the study was at least one year. Study variables were recorded in patients’ clinical histories and in an electronic database (Excel), and all data were collected in a Case Report Form (CRF) for the epidemiological analysis by the physician responsible for the patient.  |
| Participants | 6 | (*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up | Page 7 (lines 178-185); The study included IBD patients treated with Remsima® (infliximab biosimilar, CT-P13, Kern Pharma, Spain) in clinical practice who were naïve to biological treatments, or with failure to respond to other anti-TNF drugs, or who had switched from infliximab (Remicade®). 12 months of follow-up but no diagnostic or follow-up interventions were conducted on patients outside of the usual clinical practice.  |
| (*b*)For matched studies, give matching criteria and number of exposed and unexposed |  |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | Page 7-8 (lines 188-211); The primary endpoint was clinical response rates and number of adverse events in IBD patients treated with CT-P13 (Remsima®) in real-life practice. Variables were collected at baseline and every three months during 12 months of follow-up. CT-P13 (Remsima®) trough levels and anti-drug antibodies were determined according to clinical practice before each infusion. The primary efficacy variable was the proportion of patients who were in clinical remission and/or had a clinical response at each visit. |
| Data sources/ measurement | 8\* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | Page 8 (lines 195-108); It was considered active clinical disease when HBI (Harvey-Bradshaw Index) >4 (CD) or PMS (Partial Mayo Score) >2 (UC) or active fistula. A fistula was considered active if it presented suppuration spontaneously or with digital pressure, and inactive if there was no suppuration. It was considered clinical remission when HBI ≤4 (CD) or PMS ≤2 (UC) or inactive fistula. A clinical response was considered when there was a decrease of at least 2 points in HBI or PMS or improvement of fistula. The disease was considered stable when HBI ≤4 (CD) or PMS ≤ 2 (UC) and C-reactive protein (CRP) <5 mg/L for at least 6 months. Relapse or exacerbation was defined by the need to scale the dosage of CT-P13 (Remsima®) (shorten interval and/or increased doses), the addition of corticosteroids, or switching to another biologic agent based on the physician's decision. Loss of response was defined as active disease after primary response after at least the first four infusions of the biologic drug. The safety variable was the number of adverse effects described in the follow-up. |
| Bias | 9 | Describe any efforts to address potential sources of bias | Page 6 (lines 156-159). No diagnostic or follow-up interventions were conducted on patients outside of the usual clinical practice, |
| Study size | 10 | Explain how the study size was arrived at | Page 8 (line 222); Sample size was not defined. |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | Page 8 (lines 225-226); The results for categorical variables were presented as frequencies and percentages. |
| Statistical methods | 12 | (*a*) Describe all statistical methods, including those used to control for confounding | Page 8 (lines 223-228); a) A descriptive analysis of all the variables of interest was made. The results of continuous variables were presented as mean and standard deviation (SD). The statistical analysis included appropriate measures for statistical significance (Student’s paired two-sample t-test) using the standard cutoff for significance of *p<0.05* via Microsoft Excel.b) No subgroupsc) No missing datad) ---------- |
| (*b*) Describe any methods used to examine subgroups and interactions | e) N/A |
| (*c*) Explain how missing data were addressed |  |
| (*d*) If applicable, explain how loss to follow-up was addressed |  |
| (*e*) Describe any sensitivity analyses |  |
| Results |  |
| Participants | 13\* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | Pages 8-9 (lines 230-312); a) A total of 220 IBD patients treated with CT-P13 (Remsima®) were included in the study: 87 (40%) with UC and 133 (60%) with CD. At the time of starting CT-P13 (Remsima®) treatment, mean age of patients was 41.47 (SD 15.74). They were well distributed by gender: 42% were male and 58% were female. Most patients (140, 63.6%) were non-smokers, 37 (16.8%) were smokers, and 28 (12.8%) were former smokers. b) Page 7 (lines 181-183); Patients who were unresponsive to infliximab or allergic or intolerant to infliximab or its excipients, or had a contraindication to infliximab were excluded. |
| (b) Give reasons for non-participation at each stage | c) N/A |
| (c) Consider use of a flow diagram |  |
| Descriptive data | 14\* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | a) Page 7 (lines 178-181); The study included IBD patients treated with Remsima® (infliximab biosimilar, CT-P13, Kern Pharma, Spain) in clinical practice who were naïve to biological treatments, or with failure to respond to other anti-TNF drugs, or who had switched from infliximab (Remicade®).b) N/Ac) page 10 (line 262-263); One year follow up. |
| (b) Indicate number of participants with missing data for each variable of interest |  |
| (c) Summarise follow-up time (eg, average and total amount) |  |
| Outcome data | 15\* | Report numbers of outcome events or summary measures over time | N/A |

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| Main results | 16 | (*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | ------------- |
| (*b*) Report category boundaries when continuous variables were categorized |  |
| (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period |  |
| Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | N/A |
| Discussion |
| Key results | 18 | Summarise key results with reference to study objectives | Pages 12-14 (lines 314-388); Discussion |
| Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | Page 12 (352-355); Unequal number of patients, (359-361)available data heterogeneous across visits. |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | Page 12-14 (lines 314-388); Discussion |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | Pages 14 (lines 385-388); CT-P13 (Remsima®) is an effective and safe biosimilar of infliximab for the treatment of CD and UC in real-life practice, being a valid and attractive alternative for the treatment of IBD, since it allows reducing healthcare costs and facilitates access to biological treatments for more patients. |
| Other information |
| Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | Page 2 (lines 38-39); Kern Pharma Laboratories provided funds for the statistical analysis and article writing. |

\*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.