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Title:
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Dear Editor:

A new subcutaneous formulation of the infliximab biosimilar CT-P13 has recently been developed for the treatment of inflammatory bowel disease (IBD), providing response rates similar to intravenous treatment, (1-3). In an effort to limit patient attendance at intravenous infusion centers and to maintain biological treatment during the COVID-19 pandemic, the use of this new formulation was requested. The objective of this observational, retrospective, and descriptive study was to assess CT-P13 efficacy and safety after switching from intravenous to subcutaneous formulation in patients with IBD receiving maintenance therapy. This article shows preliminary results after six months of follow-up.

Due to the emergency of the COVID-19, 17 patients with IBD (70.6% Crohn's disease and 29.4% ulcerative colitis) in clinical remission switched intravenous to subcutaneous CT-P13 (Remsima®, 120 mg every 2 weeks in pre-filled pen) and were included in the study. All of them had been treated with stable doses of intravenous CT-P13 every 8 weeks for a median of 45 months.

Disease and treatment related variables were compared between baseline (intravenous CT-P13) and 12 and 24 weeks after starting the treatment with subcutaneous CT-P13. The only significant differences observed was a decrease in the Clinical Mayo Score, a decrease in fecal calprotectin levels, and an increase in serum drug concentration (Table 1). Further studies with a greater number of patients are needed to detect clinical relevance in the latter finding. No serious adverse effects were notified that conditioned the discontinuation of the drug.

The new subcutaneous formulation of CT-P13 is a further step towards a more individualized therapy, providing a more practical route of administration and a potential benefit on the drug's serum concentrations. All this offers great advantages to IBD patients, both in terms of therapeutic flexibility and less dependence on infusion centers.

Author's contribution

Federico Argüelles-Arias: Project management, conceptualization, review and editing the manuscript writing, research, methodology, supervision.

Paula Fernández Álvarez: formal analysis, data retention, writing the first draft, review and editing the manuscript writing, research, methodology.

Luisa Castro Laria: review and editing the manuscript writing.

Belén Maldonado Pérez: review and editing the manuscript writing.

María Belvis Jiménez: review and editing the manuscript writing.

Vicente Merino-Bohórquez: review and editing the manuscript writing.

Ángel Caunedo Álvarez: review and editing the manuscript writing.

Miguel Ángel Calleja: review and editing the manuscript writing.

Conflicts of interest

Federico Argüelles-Arias has served as a speaker, consultant and advisory member for or have received research funding from Janssen, MSD, AbbVie, Pfizer, Kern Pharma, Biogen, Sandoz, Takeda, Ferring, Faes Farma, Shire Pharmaceuticals, Dr. Falk Pharma, Tillotts Pharma, Gebro Pharma, Amgen, and Vifor Pharma.

Paula Fernández Álvarez do not have any type of conflict of interest, nor any economic, personal, political, financial or academic interest that may influence our judgment.

Luisa Castro Laria do not have any type of conflict of interest, nor any economic, personal, political, financial or academic interest that may influence our judgment.

Belén Maldonado Pérez do not have any type of conflict of interest, nor any economic, personal, political, financial or academic interest that may influence our judgment.

María Belvis Jiménez has received research funding from Pfizer.

Vicente Merino-Bohórquez has received research funding from Pfizer, Kern, AbbVie, Janssen-Cilag, and Amgen.

Ángel Caunedo Álvarez do not have any type of conflict of interest, nor any economic, personal, political, financial or academic interest that may influence our judgment.

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Table 1. Comparative analysis of efficacy between intravenous and subcutaneous formulation

Variable	**Basal** **IFX IV** **(n=17)**	**Week 12** **IFX SC** **(n=17)**	**Week 24** **IFX SC** **(n=17)**	**p**
CRP (mg/L)	1.6 (0.4;4.0)	0.8 (0.4;2.3)	1.4 (0.4;2.2)	0.257
ESR (mm/h)	10 (5.5;20.5)	10 (7.5;19.5)	9.5 (5.0;19.0)	0.545
Fecal calprotectin (µg/g) • Total • CD • UC	 258.35 (81.3;357.0) 274.2 (79.2;342.0) 148.0 (104.0;367.5)	 135 (50.3;269.6) 138.0 (48.5;509.1) 132.0 (37.8;234.0)	 59.5 (26.8;199.8) 50.0 (36.7;227.0) 74.0 (20.3;243.0)	 0.028 0.276 0.078
Harvey-Bradshaw Index	2 (2;3)	2 (1;3)	2 (1;2)	0.422
Clinical or partial Mayo Index	1 (1;2)	0 (0;1)	0 (0;1.5)	0.015
Drug concentration (µg/ml)	6.1 (3.5;8.9)	18.1 (15.5;21.2)	19,9 (12.3;21.6)	< 0.001
Concomitant treatments: • Salicylates • Immunomodulators • Corticoids	 10 (58.8%) 9 (52.9%) 0 (0%)	 9 (52.9%) 9 (52.9%) 1 (5.9%)	 6 (50.0%) 4 (36.4%) 0 (0%)	 0.500 > 0.999 -
Clinical Remission	17 (100%)	15 (88.2%)	15 (88.2%)	0.466

Quantitative measurements are expressed as median (interquartile range).

IFX: infliximab; IV: intravenous; CRP: C-reactive protein; SC: subcutaneous; ESR: erythrocyte sedimentation rate