

Supplementary text:

Patient-reported outcomes

In addition to the outcomes included in the clinical activity indices, QoL and work productivity were evaluated. Assessment of QoL was undertaken using the shortened Spanish version of the Inflammatory Bowel Disease Questionnaire 9 (CCVEII-9 QoL questionnaire), and work productivity and activity was assessed using the Spanish Work Productivity and Activity Impairment (WPAI) questionnaire.

Laboratory assessments

Blood samples were taken for haematology and biochemistry profiles. In addition, faecal samples were obtained at baseline and at every visit during follow-up. Drug and antidrug levels were determined by enzyme-linked immunosorbent assay (ELISA) using Promonitor[®] corresponding product, following package insert instructions. Faecal samples were extracted using CALEX[®] Cap Extraction device from BÜHLMANN Laboratories AG, Switzerland. The CALEX[®] Cap is a single tube filled with 5 ml of extraction buffer resulting in a final dilution of 1:500. Faecal calprotectin concentration was measured using the immunoturbidimetric assay BÜHLMANN fCAL[®] turbo on a BA200 analyser (BioSystems, Spain), with a measuring range of 20–8,000 µg/g and a total imprecision (CV %) of 4.0% at 85 µg/g level and 1.4% at 246 µg/g level.

Supplementary table 1. Study schedule and procedures in each study visit.

Visits	- 30 days	Baseline	Month 1	Month 2	Month 4	Month 6	Month 8	Month 10	Month 12 or clinical relapse
Informed consent		X							
Anamnesis		X							
Physical examination ^a		X	X	X	X	X	X	X	X
CDAI (CD)		X	X	X	X	X	X	X	X
Partial Mayo Score (UC)		X	X	X	X	X	X	X	X
Colonoscopy	X								X
SES-CD	X								X
Score endoscópico de Mayo	X								X
MRI enterography	X								X
Quality of life (CCVEII-9)		X	X	X	X	X	X	X	X
Productivity and working activity (Spanish-WPAI)		X	X	X	X	X	X	X	X
Lab tests		X	X	X	X	X	X	X	X
Anti-TNF and antibodies against anti-TNF serum levels		X							
Faecal calprotectin		X	X	X	X	X	X	X	X
Pregnancy test		X							
Adverse events		X	X	X	X	X	X	X	X
Concomitant medications		X	X	X	X	X	X	X	X

CCVEII-9, shortened Spanish version of the Inflammatory Bowel Disease Questionnaire 9; CD, Crohn's disease; CDAI, Crohn's disease activity index; SES-CD, Simplified endoscopic score Crohn's disease; TNF, tumour necrosis factor; UC; ulcerative colitis; WPAI, Work Productivity and Activity Impairment.

Supplementary table 2. Characteristics of the study population according to sustained clinical remission at 12 months.

	No sustained clinical remission	Sustained clinical remission	p
Mean age at inclusion (years), SD	43.0 (31.2-51.4)	43.4 (31.2-50.7)	0.7
Median time under current anti-TNF (years), IQR	2.8 (1.4-5.6)	2.6 (1.3-5.3)	0.9
Median time in remission with current anti-TNF at standard dose (months), IQR	15.6 (9.7-50)	23.4 (11.7-36.7)	0.6
Median time under immunomodulators (months), SD	32.8 (16.8-72.4)	27.6 (13.3-59.9)	0.3
Male gender, n (%)	16 (57)	72 (64.3)	0.4
Crohn's disease, n (%)	11 (39.3)	51 (45.4)	
L1, n (%)	1 (9)	16 (31)	0.1
L2, n (%)	2 (18)	15 (29)	
L3, n (%)	8 (73)	20 (39)	
L4, n (%)	0 (0)	4 (8)	0.34
B1, n (%)	9 (82)	40 (78)	0.8
B2, n (%)	2 (18)	9 (18)	
B3, n (%)	0 (0)	4 (8)	
Perianal, n (%)	1 (9)	3 (6)	0.6
Ulcerative colitis, n (%)	17 (60.7)	61 (54.5)	0.5
Extensive, n (%)	10 (59)	40 (66)	0.5
Left-sided, n (%)	7 (41)	19 (31)	
Proctitis, n (%)	0 (0)	2 (3)	
Type of anti-TNF			
Adalimumab, n (%)	3 (10.7)	16 (14.3)	0.6
Infliximab, n (%)	25 (89.3)	96 (85.7)	
Indication for the anti-TNF			
Refractoriness to immunomodulators, n (%)	7 (25)	34 (30.4)	0.8
Steroid-dependency, n (%)	11 (39.3)	38 (33.9)	
Steroid-refractoriness, n (%)	7 (25)	21 (18.8)	
Top-down strategy, n (%)	1 (3.6)	5 (4.5)	
Others, n (%)	2 (7.1)	14 (12.5)	
Prior intensification of current anti-TNF, n (%)	7 (25)	17 (15)	0.2
Median CDAI, IQR	7.1 (0-31.7)	15.7 (0-31.3)	0.8
Median Partial Mayo Score, IQR	0 (0-0)	0 (0-0)	0.1
Median SES-CD, IQR	0 (0-1)	0 (0-0)	0.3
Median Mayo endoscopic subscore, IQR	0 (0-0)	0 (0-0)	0.1
Median C-reactive protein (mg/L), IQR	0.2 (0.1-0.5)	0.1 (0.1-0.3)	0.09
Mean haemoglobin (g/dL), SD	14.5 (0.2)	14.4 (0.1)	0.5
Mean albumin (g/dL), SD	4.4 (0.08)	4.4 (0.03)	0.7
Faecal calprotectin >250 µg/g, n (%)	7 (28)	8 (8)	0.007
Median adalimumab serum level (µg/mL), IQR	8.1 (4-8.3)	14.4 (9.8-17.3)	0.3
Median infliximab serum level (µg/mL), IQR	3.9 (2.2-8.02)	5.1 (3-8.7)	0.2

SD, standard deviation; TNF, tumour necrosis factor; IQR, interquartile range; CDAI, Crohn's disease activity index; SES-CD, Simplified endoscopic score of Crohn's disease.

Supplementary table 3. Proportion of patients with paid employment during follow-up (observed values).

	Maintenance arm	Withdrawal arm
Baseline, n (%)	47 (67)	54 (77)
Month 1, n (%)	44 (65)	54 (78)
Month 2, n (%)	47 (68)	51 (75)
Month 4, n (%)	43 (64)	49 (77)
Month 6, n (%)	42 (67)	47 (81)
Month 8, n (%)	43 (69)	43 (77)
Month 10, n (%)	41 (68)	39 (71)
Month 12, n (%)	42 (64)	43 (63)

Supplementary table 4. Proportion of patients who declared no impact of their health problems on life activities during follow-up (observed values).

	Maintenance arm	Withdrawal arm
Baseline, n (%)	46 (66)	43 (61)
Month 1, n (%)	47 (69)	41 (60)
Month 2, n (%)	46 (67)	45 (67)
Month 4, n (%)	47 (70)	42 (67)
Month 6, n (%)	41 (65)	41 (71)
Month 8, n (%)	39 (67)	39 (70)
Month 10, n (%)	41 (68)	38 (69)
Month 12, n (%)	40 (61)	40 (61)

n.s., not statistically significant.

Supplementary table 5. Impact of health issues on work productivity based on the CCVEII-9 questionnaire throughout the study period (12 months) (observed values).

- a. During the last seven days, how many hours of work did you lose due to your health issues?

	Maintenance arm	Withdrawal arm
Baseline, median (IQR)	0 (0-0)	0 (0-0)
Month 1, median (IQR)	0 (0-0)	0 (0-0)
Month 2, median (IQR)	0 (0-0)	0 (0-0)
Month 4, median (IQR)	0 (0-0)	0 (0-0)
Month 6, median (IQR)	0 (0-0)	0 (0-0)
Month 8, median (IQR)	0 (0-0)	0 (0-0)
Month 10, median (IQR)	0 (0-0)	0 (0-0)
Month 12, median (IQR)	0 (0-0)	0 (0-0)

- b. During the last seven days, how many hours of work did you lose due to any other reason, including study participation?

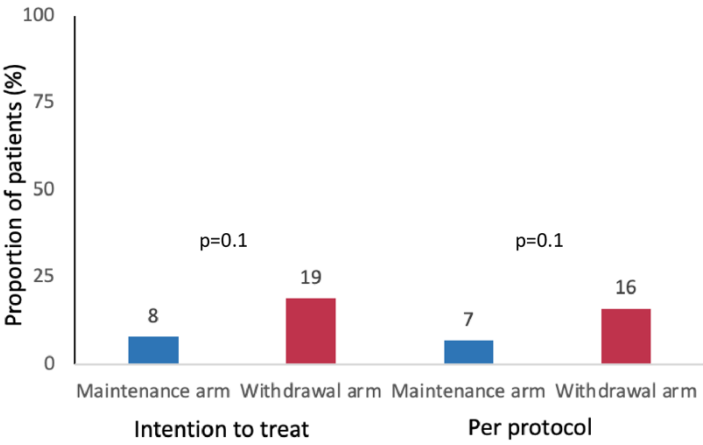
	Maintenance arm	Withdrawal arm
Baseline, median (IQR)	0 (0-6)	0 (0-5)
Month 1, median (IQR)	0 (0-0)	0 (0-2)
Month 2, median (IQR)	0 (0-2)	0 (0-3)
Month 4, median (IQR)	0 (0-3)	0 (0-1)
Month 6, median (IQR)	0 (0-8)	0 (0-3)
Month 8, median (IQR)	0 (0-3)	0 (0-3)
Month 10, median (IQR)	0 (0-4)	0 (0-4)
Month 12, median (IQR)	0 (0-7)	0 (0-1)

- c. During the last seven days, how many hours did you actually work?

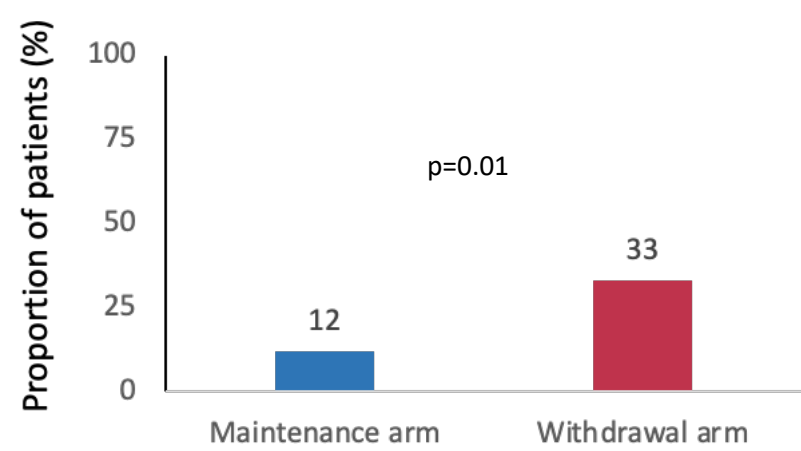
	Maintenance arm	Withdrawal arm
Baseline, median (IQR)	40 (30-44)	40 (31-40)
Month 1, median (IQR)	40 (27-45)	40 (28-40)
Month 2, median (IQR)	40 (21-40)	40 (35-40)
Month 4, median (IQR)	40 (35-40)	40 (35-40)
Month 6, median (IQR)	38 (17-40)	40 (32-40)
Month 8, median (IQR)	40 (32-40)	40 (32-40)
Month 10, median (IQR)	40 (28-40)	40 (32-40)
Month 12, median (IQR)	40 (28-40)	40 (35-40)

CCVEII-9, CCVEII-9, shortened Spanish version of the Inflammatory Bowel Disease Questionnaire 9; IQR, interquartile range; n.s., not statistically significant.

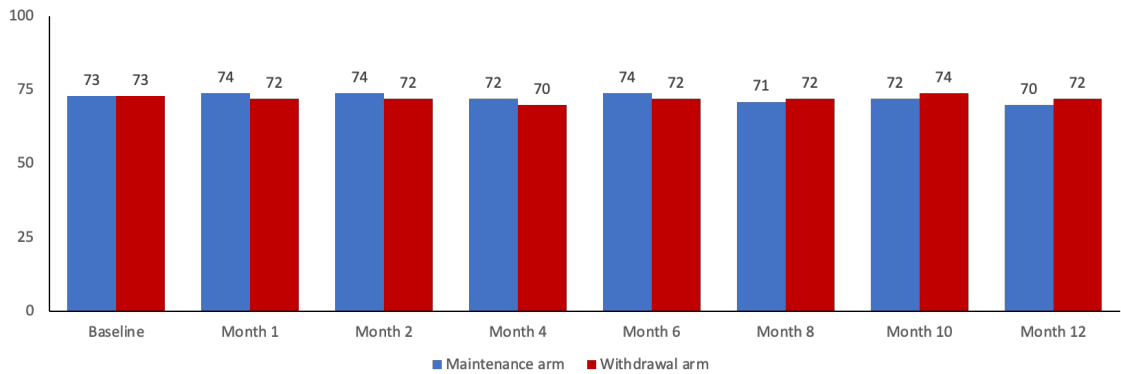
Supplementary figure 1. Significant endoscopic lesions at the end of follow-up (12 months or early termination).



Supplementary figure 2. Faecal calprotectin >250 µg/g at the end of follow-up (12 months or early termination).



Supplementary figure 3. Quality of life measured by the CCVEII-9 questionnaire throughout the follow-up.



Median value in the CCVEII-9 questionnaire at baseline (normal distribution) and median value thereafter.

CCVEII-9, shortened Spanish version of the Inflammatory Bowel Disease Questionnaire 9.