neoTrial

Clinical Data Management System

Demo Clinical Trial Protocol

IBD-321

A Phase 2, randomized, double-blind, placebo-controlled, multi-center study to evaluate bi-weekly subcutaneous self-injection IBD-321 in adult subjects with active ulcerative colitis

Version 1.0 – 18-Aug-2022

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*This document is not a real clinical study, but produced on the base of a real protocol of the (typical) oncology study in patients with breast cancer to reflect the study examinations/procedures which are possible to be managed in the **neoTrial** System.*

Clinical Study Details

Sponsor	IBD Pharma Inc.
Study Number	IBD-321-001
Version	1.0
Date Final	18-Aug-2022
Study Drug	IBD-321
Inclusion Criterion	A Phase 2, randomized, double-blind, placebo-controlled, multi-center study to evaluate bi-weekly subcutaneous self-injection IBD-321 in adult subjects with active ulcerative colitis
Enrollment Point	Visit 2
Planned Enrollment	40 enrolled patients
Clinical Study Sites	5
Expected completed patients	40
Expected questionnaires IBD Control	500
Study Periods	1. Screening – 14-28 days 2. Study Treatment (Enrollment) – 294 days 3. Follow-Up – 20 days

Table 1. Schedule of the Study Events

	Screening	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Early Discontinuation (optional)	Unscheduled (optional)	EOS	Follow-Up 1	Follow-Up 2
Week	**-4 - -2**	**0**	**2**	**4**	**8**	**12**	**18**	**24**	**30**	**36**			**42**	**48**	**52**
Day	**'-28 - -14**	**1**	**14**	**28**	**56**	**84**	**126**	**168**	**210**	**252**			**294**	**336**	**364**
Visit Window ± days			**3**	**3**	**3**	**3**	**3**	**3**	**3**	**3**			**3**	**3**	**3**
eConsent - Informed consent	X														
12-lead ECG	X		X			X				X	X	X	X		
Colonoscopy	X					X					X	X	X		
Chest X-Ray	X										X	X	X		
eQuestionnaire IBD Control	X	X	X	X	X	X	X	X	X	X			X	X	X
AE eDiary	X														
eDiary Patient's Simple Clinical Colitis Activity Index	**Weekly (Screened, Enrolled)**														
eDiary VAS after the self-injection		**Bi-Weekly**													
eQuestionnaire Self-Injection Assessment Checklist (for physician)			X	X		X				X					

Appendix 1. Inflammatory Bowel Disease Questionnaire – IBD Control

IBD Control

Inflammatory Bowel Disease Control Questionnaire

1 Do you believe that:

	Yes	No	Not sure
a. Your IBD has been well controlled in the past *two weeks* ?	☐	☐	☐
b. Your *current treatment* is useful in controlling your IBD?	☐	☐	☐

(If you are not taking any treatment, please tick this box ☐)

2 Over the past 2 weeks, have your bowel symptoms been getting worse, getting better or not changed?	Better	No change	Worse
	☐	☐	☐

3 In the past 2 weeks, did you:

	Yes	No	Not sure
a. Miss any planned activities because of IBD? (e.g. attending school/college, going to work or a social event)	☐	☐	☐
b. Wake up at night because of symptoms of IBD?	☐	☐	☐
c. Suffer from significant pain or discomfort?	☐	☐	☐
d. Often feel lacking in energy (fatigued) (by 'often' we mean more than half of the the time)	☐	☐	☐
e. Feel anxious or depressed because of your IBD?	☐	☐	☐
f. Think you needed a change to your treatment?	☐	☐	☐

4 At your next clinic visit, would you like to discuss:

	Yes	No	Not sure
a. Alternative types of drug for controlling IBD	☐	☐	☐
b. Ways to adjust your own treatment	☐	☐	☐
c. Side effects or difficulties with using your medicines	☐	☐	☐
d. New symptoms that have developed since your last visit	☐	☐	☐

5 How would you rate the OVERALL control of your IBD in the past *two weeks*?

Please draw a vertical line (|) on the scale below

Appendix 2. Patient-based Simple Clinical Colitis Activity Index (P-SCCAI).

Patient-based Simple Clinical Colitis Activity Index (P-SCCAI)

For patients

This questionnaire refers to disease symptoms during the previous week. It is composed of six domains: bowel frequency (during the day) ranging from 1 to > 9; bowel frequency (during the night) ranging from 0 to 6; urgency of defecation ranging from none to incontinence; blood in stool ranging from none to usually frank (> 50% of defecation); general well-being ranging from very well to terrible (1–10) and a number of defined extracolonic features of UC (i.e. arthritis, erythema nodosum, pyoderma gangrenosum, uveitis). The four latter questions have a 'yes' or 'no' option. After recoding, the clinician-based SCCAI is able to categorize two types of patients: patients with inactive disease (SCCAI score < 5) and patients with active disease (SCCAI score ≥ 5).

This patient-modified P-SCCAI was devised by two medical psychologists, one research assistant and one gastroenterologist. All items within the P-SCCAI refer to symptoms during the previous week and were translated into patients' comprehensible language. Medical terminology and disease symptoms were clarified. For example, "uveitis" is described as "eye infection, which your specialist diagnosed as uveitis".

Variable	Description	Scoring	
1	Bowel frequency (day)	n (1 per occurrence)	
		0 – 3	(score 0)
		4 – 6	(score 1)
		7 – 9	(score 2)
		> 9	(score 3)
2	Bowel frequency (night)	0	(score 0)
		1 – 3	(score 1)
		4 – 6	(score 2)
3	Urgency of defecation	None	(score 0)
		Hurry	(score 1)
		Immediately (toilet nearby)	(score 2)
		Incontinence	(score 3)
4	Blood in stool	None	(score 0)
		Trace	(score 1)
		Occasionally frank (<50% of defecation)	(score 2)
		Usually frank (>50% of defecation)	(score 3)
5	General well-being (0 – 10)	≥ 7 = very well	(score 0)
		6 = slightly below par	(score 1)
		5 = poor	(score 2)
		4 = very poor	(score 3)
		< 4 = terrible	(score 4)
6	Extracolonic features	1 per manifestation:	
		Arthritis	Yes = 1 No = 0
		Uveitis	Yes = 1 No = 0
		Erythema nodosum	Yes = 1 No = 0
		Pyoderma gangrenosum	Yes = 1 No = 0

Appendix 3. Self-Injection Assessment Checklist

Self-Injection Assessment Checklist

To be completed by investigator

No.	Instructions for Use	Completion Required for Successful Administration? (Yes/No)
P1	Removed the auto-injector from the carton	
P2	Inspected the auto-injector for damage and expiration date	
P3	Inspected the liquid for any particles	
P4	Left the auto-injector at room temperature for at least 30 minutes	
P5	Selected the injection site from the front of the thighs or the abdomen (except 5cm around navel)	
P6	Washed hands with soap and water	
P7	Cleaned the injection site with an alcohol swab without blowing or touching injection site again	
P8	Removed the Cap by pulling straight off	
P9	Placed the auto-injector at 90° angle over the injection site without pinching or stretching the skin	
P10	Pressed the auto-injector firmly against the skin to start the injection (1st click), and kept holding the auto-injector firmly against the skin until the 2nd click	
P11	Continued to hold the auto-injector firmly against the skin after the 2nd loud click and counted slowly to 5 to ensure injecting the full dose	
P12	Removed the auto-injector and checked if the window was filled completely with olive green Plunger Rod	

Appendix 4. Visual Analogue Scale (VAS): Local Site Pain

Visual Analogue Scale (VAS): Local Site Pain

Patient assessment of local site pain is measured by the patient indicating the extent of their pain in the local site where study drug was administered by marking one line (|) through the scale line (0 equals no pain and 100 equals extreme pain).
Note: Local site pain will be assessed immediately (not exceeding 15 minutes) after the end of administration of study drug.