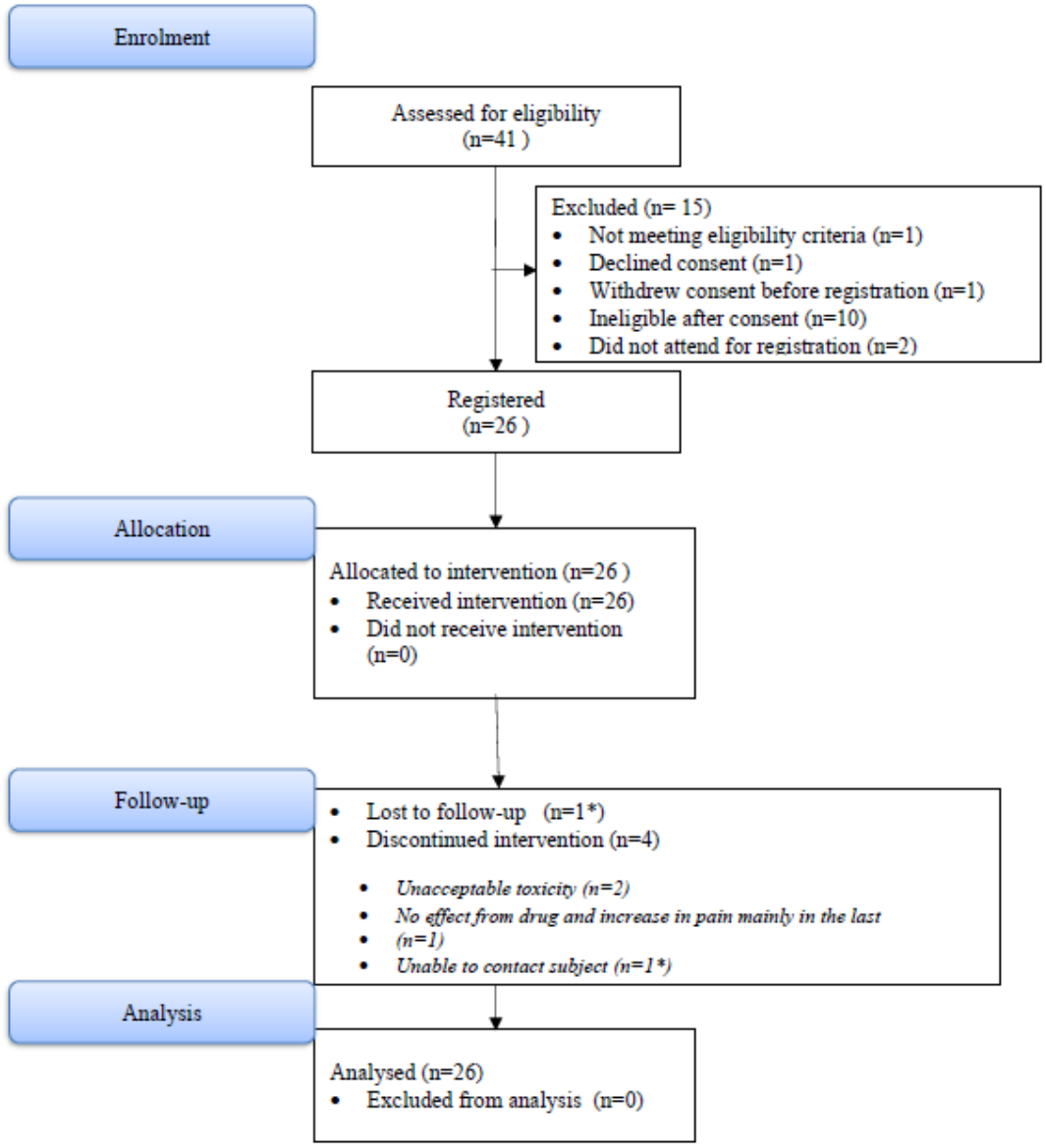
Participant Flow



**One participant was withdrawn from both treatment and follow-up when they were unable to be contacted.*

Baseline Characteristics

	Overall
Age (years)	
N	26
Mean (Sd)	38.4 (10.5)
Median (IQR, LQ, UQ)	37 (17, 30, 47)
(Minimum, Maximum)	(19, 58)
Missing	0
Age (years): n(%)	(N=26)
Adults (18-64 years)	26 (100%)
From 65 to 84 years	0
85 years and over	0
Missing	0
Gender: n (%)	(N=26)
Male; n (%)	3 (11.5%)
Female; n (%)	23 (88.5%)
missing	0
Ethnicity	
Arab; n (%)	0
Asian Other; n (%)	0
Bangladeshi; n (%)	0
Black African; n (%)	0
Black Caribbean; n (%)	1 (3.8%)
Black Other; n (%)	0
Chinese; n (%)	0
Gypsey or Irish Traveller; n (%)	0
Indian; n (%)	0
Irish; n (%)	0
Other ethnic group; n (%)	0
Other mixed; n (%)	0
Other white; n (%)	1(3.8%)
Pakistani; n (%)	0
White and Asian; n (%)	0
White and Black African; n (%)	0
White and Black Caribbean; n (%)	1 (3.8%)
White British; n (%)	23 (88.5%)
Missing	0

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Primary Outcome Summary

	Overall
Number of participants	26
At least one serious AE experienced	
Yes; n (%)	0
No; n (%)	26 (100%)
If Yes, the number experienced	
N	NA
Mean (Sd)	NA
Median (IQR, LQ, UQ)	NA
(Minimum, Maximum)	NA
Missing	NA
At least one condition specific AE experienced	
Yes; n (%)	1 (3.8%)
No; n (%)	25 (96.2%)
If Yes, the number experienced	
N	1
Mean (Sd)	3 (NA)
Median (IQR, LQ, UQ)	3(0,3,3)
(Minimum, Maximum)	(3, 3)
Missing	0
At least one serious or condition specific AE experienced	
Yes; n (%)	1 (3.8%)
No; n (%)	25 (96.2%)
If Yes, the number experienced	
N	1
Mean (Sd)	3 (NA)
Median (IQR, LQ, UQ)	3 (0,3,3)
(Minimum, Maximum)	(3, 3)
Missing	0
Proportion experiencing at least one serious or condition specific AE	3.8
Proportion experiencing no serious or condition specific AE	96.2

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Non-Serious adverse events / reactions

There were a total of 176 non-serious adverse events/reactions reported by 25 of the 26 patients in the safety population (all patients who received at least one dose).

	Total	
System Organ class	Events n	Patients n (%)
Blood and lymphatic system disorders	2	1 (3.8%)
Cardiac disorders	2	2 (7.7%)
Eye disorders	1	1 (3.8%)
Gastrointestinal disorders	27	15 (57.7%)
General disorders and administration site conditions	50	22 (84.6%)
Hepatobiliary disorders	1	1 (3.8%)
Infections and infestations	28	17 (65.4%)
Injury, poisoning and procedural complications	3	2 (7.7%)
Investigations	5	4 (15.4%)
Metabolism and nutrition disorders	1	1 (3.8%)
Musculoskeletal and connective tissue disorders	17	8 (30.8%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	1 (3.8%)
Nervous system disorders	19	13 (50.0%)
Psychiatric disorders	3	2 (7.7%)
Respiratory, thoracic and mediastinal disorders	5	5 (19.2%)
Skin and subcutaneous tissue disorders	11	8 (30.8%)
Total	**176**	**25 (96.2%)**

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Serious adverse events/reactions

No SAEs occurred for any of the 26 participants who were registered on the trial and commenced treatment.

There was 1 SAE which occurred for a patient who had consented but prior to registration on the trial and which made the patient ineligible. Therefore, relatedness and expectedness were not assessed. This SAE is detailed in Table 14-4.

Line listing of serious adverse events/reactions

SAE/R Number	System Organ Class	Preferred Term	Onset Date	Serious Criteria		Severity (PI assessment)	Expectedness (CI assessment)	Relationship		Most likely cause, if unrelated (PI assessment)	Outcome
				PI assessment	CI assessment			PI assessment	CI assessment		
001	Respiratory, thoracic and mediastinal disorders	Pulmonary Mass	23/08/2022	Important Medical Event-Adenocarcinoma	.	Severe	.	Unrelated	.	Other-Incidental Finding	Not resolved/ongoing

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