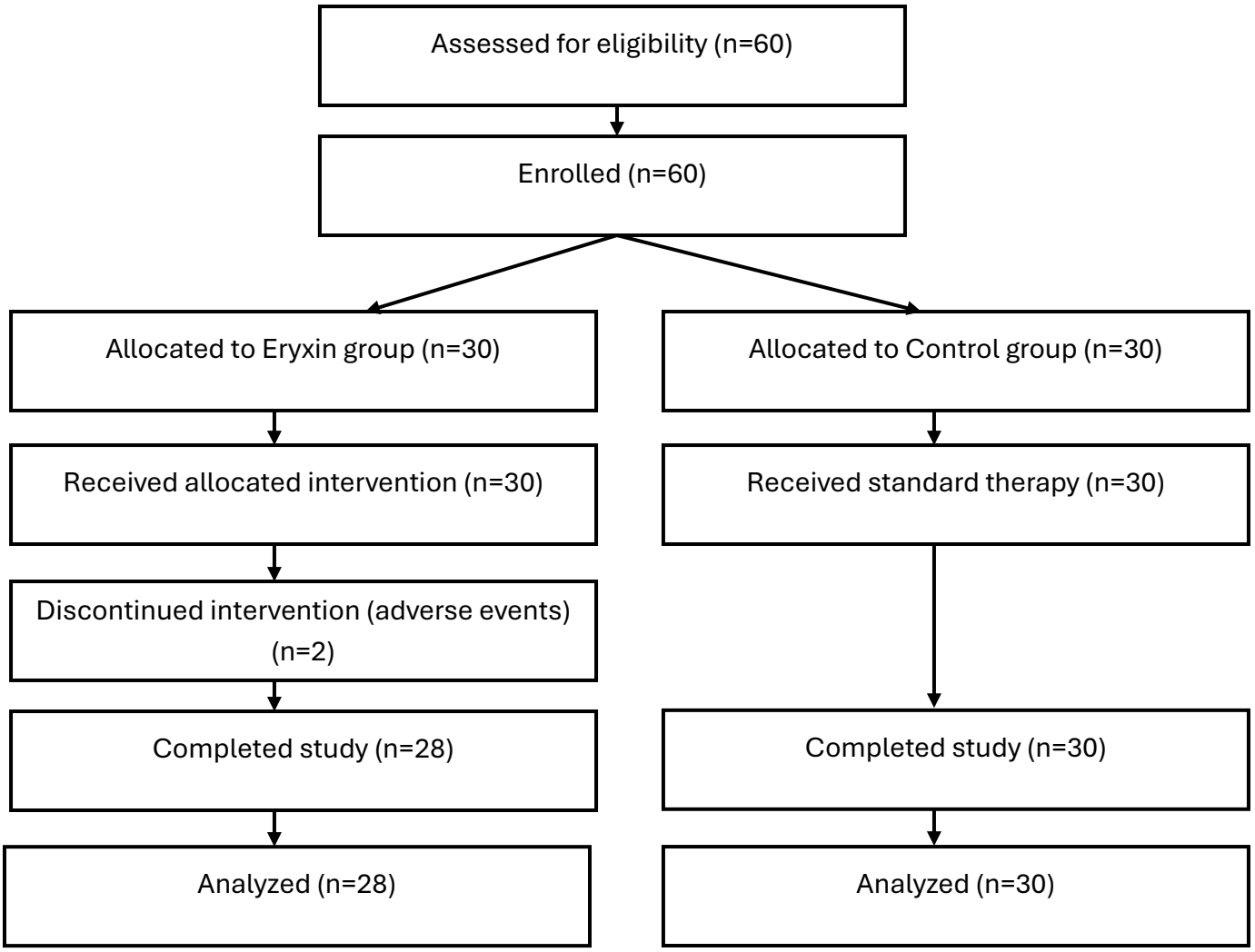
Participant Flow



Baseline characteristics

Table 1. Baseline characteristics.

Characteristic	Eryxin Group (n=30)	Control Group (n=30)
Mean age, years (±SD)	52.3 ± 10.4	49.31 ± 12.2
Female, n (%)	28 (93%)	26 (87%)
Mean disease duration, years (±SD)	6.2 ± 3.1	6.5 ± 3.4
Disease stage (Early/Moderate/Late)	3 / 10 / 17	3 / 8 / 19
Morning stiffness (minutes)	64.0 ± 4.43	64.5 ± 5.14
Number of tender joints	3.2 ± 1.63	3.1 ± 1.52
Number of swollen joints	2.73 ± 0.44	2.73 ± 0.45
Baseline DAS28 (mean ± SD)	4.41 ± 0.54	4.33 ± 0.7
Baseline VAS pain score (mean ± SD)	6.9 ± 1.84	7.43 ± 1.47
Systolic BP	133.75±14.1	124.48±15.3
Diastolic BP	86.63±5.8	80.52±8.7
Heart Rate	88.5±3.7	87.34±11.8
Body temperature	36.7±0.6	36.64±0.7
Respiratory rate	18.38±1.6	17.24±2.0

Primary and secondary Outcomes

Table 2. Primary Outcomes at Baseline and Day 30

Outcome	Eryxin Group (Baseline)	Eryxin Group (Day 30)	Control Group (Baseline)	Control Group (Day 30)
Morning stiffness (minutes)	64.0 ± 4.43	15.0 ± 5.2	64.5 ± 5.14	21.9 ± 7.5
Number of tender joints	3.2 ± 1.63	1.0 ± 0.82	3.1 ± 1.52	2.1 ± 1.32
Number of swollen joints	2.73 ± 0.44	0.39 ± 0.5	2.73 ± 0.45	1.77 ± 0.68
VAS pain score (0-10 cm)	6.9 ± 1.84	1.25 ± 0.65	7.43 ± 1.47	5.03 ± 1.5
DAS28	4.41 ± 0.54	2.53 ± 0.51	4.33 ± 0.7	3.67 ± 0.66

Note: Data are presented as mean ± standard deviation (SD).

Table 3. Secondary Outcomes at Baseline and Day 30

Outcome	Eryxin Group (Baseline)	Eryxin Group (Day 30)	Control Group (Baseline)	Control Group (Day 30)
Heart rate (beats per minute)	88.5 ± 3.7	82.93 ± 5.2	87.34 ± 11.8	82.03 ± 8.1
Respiratory rate (breaths per minute)	18.38 ± 1.6	16.45 ± 1.8	17.24 ± 2.0	16.76 ± 2.2
Systolic blood pressure (mmHg)	133.75 ± 14.1	120.34 ± 8.3	124.48 ± 15.3	126.90 ± 8.1
Diastolic blood pressure (mmHg)	86.63 ± 5.8	77.86 ± 9.0	80.52 ± 8.7	80.86 ± 4.6
Body temperature (°C)	36.7 ± 0.6	36.51 ± 0.7	36.64 ± 0.7	36.5 ± 0.7
ESR (mm/h)	26.37 ± 8.0	15.9 ± 3.7	22.21 ± 11.7	18.91 ± 6.1
Leukocytes ($\times 10^9$/L)	11.07 ± 5.1	8.44 ± 0.9	9.48 ± 2.2	11.54 ± 7.9
Hemoglobin (g/L)	107.0 ± 13.2	124.93 ± 8.2	108.61 ± 17.7	108.07 ± 27.6
ALT (U/L)	38.17 ± 31.2	29.71 ± 8.1	54.09 ± 10.2	48.65 ± 10.5
AST (U/L)	32.62 ± 21.2	28.91 ± 7.8	18.00 ± 8.2	53.33 ± 5.66

Note: Data are presented as mean ± standard deviation (SD).

Table 4. Immunology Outcomes at Baseline and Day 30

Outcome	Eryxin Group (Baseline)	Eryxin Group (Day 30)	Control Group (Baseline)	Control Group (Day 30)
CD3+	57.8±6.3	51.79±6.3	55.6±10.8	56.1±7.0
CD4+	34.4±6.3	32.07±4.0	33.33±7.7	34.63±4.1
CD8+	23.6±5.1	20.5±2.9	22.37±5.6	23.0±4.0
IL-1β	1.85±0.5	1.75±0.3	1.81±0.6	1.79±0.3
IL-6	18.97±2.0	17.39±3.6	18.43±2.8	16.37±2.8
TNF-α	22.6±3.9	20.93±2.2	20.5±4.4	21.77±3.2

Note: Data are presented as mean ± standard deviation (SD).

Adverse Events

In the Eryxin group, all patients (100%) experienced mild transient symptoms (including specific odor sensation, transient tachycardia, and dyspnea), which resolved spontaneously within one minute and did not require discontinuation of therapy. Two patients (6.7%) discontinued treatment: one due to nausea, vomiting, and meteorism; and one due to exacerbation of joint pain. No serious adverse events (SAEs) were recorded.

In the control group, four patients (13.3%) reported mild adverse events: two cases of nausea and weakness, and two cases of elevated blood pressure. None of these events led to treatment discontinuation, and no serious adverse events were observed.

Table 5. Adverse events.

Adverse Event	Eryxin Group (n=30)	Control Group (n=30)
Any adverse event	30 (100%)	4 (13.3%)
Mild transient symptoms (odor, tachycardia, dyspnea)	30 (100%)	0 (0%)
Serious adverse event (SAE)	0 (0%)	0 (0%)
Discontinuation due to AE	2 (6.7%)	0 (0%)
Specific AEs: nausea, vomiting, meteorism (requiring discontinuation)	1 (3.3%)	0 (0%)
Specific AEs: exacerbation of arthritis (requiring discontinuation)	1 (3.3%)	0 (0%)
Specific AEs: nausea and weakness (mild)	0 (0%)	2 (6.7%)
Specific AEs: elevated blood pressure (mild)	0 (0%)	2 (6.7%)