Figure 1. Trial Profile

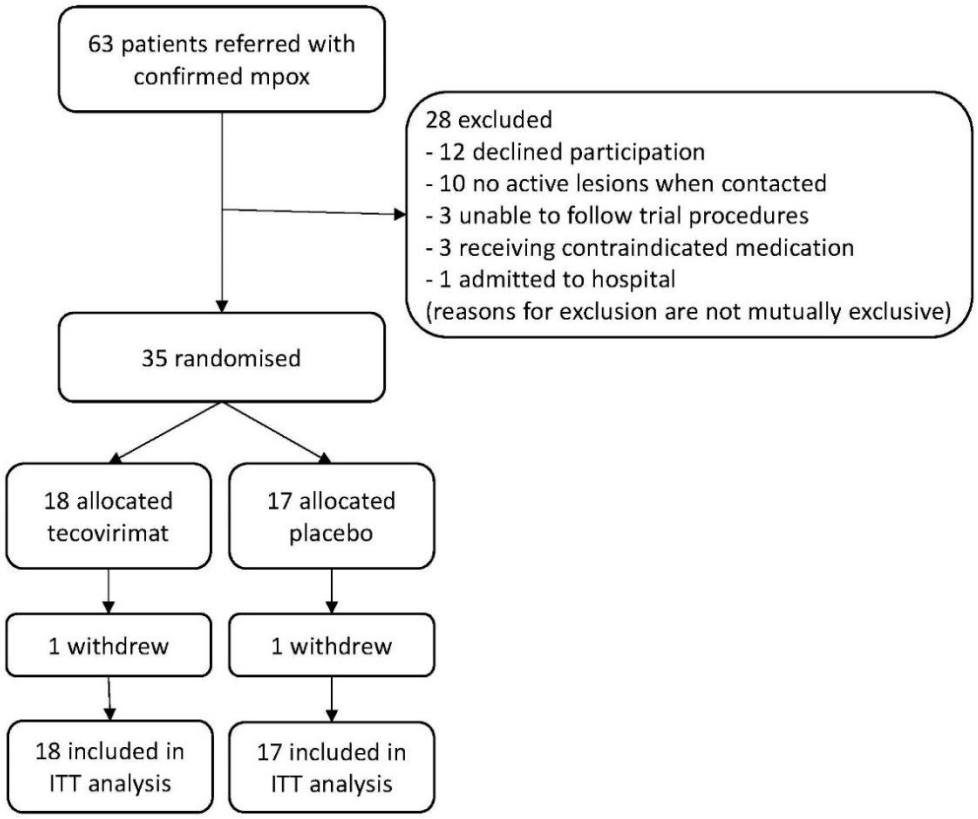

Table 1. Baseline characteristics

Characteristics	Tecovirimat (n = 18)	Placebo (n = 17)	Overall (n = 35)
Age (years), mean (SD)	37.6 (11.4)	39.0 (9.9)	38.3 (10.5)
Male sex at birth, No. (%)	18 (100)	17 (100)	35 (100)
Number of days since symptom onset, median (IQR)	7 (5-9)	7 (5-9)	7 (5-9)
Active lesions, No. (%)			
1-5	10 (55.6)	4 (23.5)	14 (40.0)
6-25	7 (38.9)	11 (64.7)	18 (51.4)
26-100	1 (5.6)	2 (11.8)	3 (8.6)
>100	0 (0.0)	0 (0.0)	0 (0.0)
New lesions in past 24 hours, No. (%)	5 (27.8)	7 (41.2)	12 (34.3)
Patients with anogenital lesions, No. (%)	16 (88.9)	17 (100.0)	33 (94.3)
Patients with mucosal lesions, No. (%)	5 (27.8)	5 (29.4)	10 (28.6)
Patients with more than one body region affected (disseminated infection), No. (%)	12 (66.7)	13 (76.5)	25 (71.4)
Systematic symptoms, No. (%)			
Fever	1 (5.6)	4 (23.5)	5 (14.3)
Swollen lymph glands	8 (44.4)	6 (35.3)	14 (40.0)
Muscle/joint pain	5 (27.8)	6 (35.3)	11 (31.4)
Sore throat	6 (33.3)	5 (29.4)	11 (31.4)
Cough	0 (0.0)	2 (11.8)	2 (5.7)
Shortness of breath	2 (11.1)	1 (5.9)	3 (8.6)
Sore eyes	2 (11.1)	2 (11.8)	4 (11.4)
Headache	3 (16.7)	5 (29.4)	8 (22.9)
Vomiting	0 (0.0)	0 (0.0)	0 (0.0)
Diarrhoea	1 (5.6)	1 (5.9)	2 (5.7)
Severe tiredness	4 (22.2)	6 (35.3)	10 (28.6)
Secondary skin infection	1 (5.6)	4 (23.5)	5 (14.3)
Pain related to skin/ mucosal lesions	16 (88.9)	12 (70.6)	28 (80.0)
Using painkillers, No. (%)	12 (66.7)	12 (70.6)	24 (68.6)
Previous diseases, No. (%)			
HIV	3 (16.7)	0 (0.0)	3 (8.6)
Other immunosuppression*	0 (0.0)	0 (0.0)	0 (0.0)
Diabetes	0 (0.0)	0 (0.0)	0 (0.0)
Previous orthopox vaccination, No. (%)			
None	12 (66.7)	10 (58.8)	22 (62.9)
Before May 2022	1 (5.6)	1 (5.9)	2 (5.7)
May 2022 or later	5 (27.8)	6 (35.3)	11 (31.4)

*Related to immunosuppressive medication or haematological disease. IQR is interquartile range. SD is standard deviation.

Table 2 Follow-up completeness and treatment adherence

Characteristics	Tecovirimat (n=18)	Placebo (n=17)	Overall (n = 35)
Follow-up completeness			
Active lesion resolution recorded by day 28 (%)	17 (94.4)	17 (100)	34 (97.1)
Complete lesion resolution recorded by day 28 (%)	15 (83.3)	16 (94.1)	31 (88.6)
50% or more daily forms completed from day 1 until active lesion resolution (%)	15 (83.3)	17 (100)	32 (91.4)
50% or more daily forms completed from day 1 until complete lesion resolution (%)	14 (77.8)	16 (94.1)	30 (85.7)
Treatment adherence			
Taking at least one dose of study treatment (%)	18 (100)	17 (100)	35 (100)
Taking study treatment on ≥7 days (%)	15 (83.3)	15 (88.2)	30 (85.7)

Table 3 Effect of allocation to tecovirimat on trial outcomes

	Tecovirimat (n=18)	Placebo (n=17)	RR, HR or OR (95% CI)	p-value
Primary outcome				
Active lesion resolution*	17 (94%)	17 (100%)	0.93 (0.42 - 2.02)	0.85
Secondary outcomes				
Complete lesion resolution†	15 (83%)	16 (94%)	0.71 (0.33 - 1.55)	0.39
Negative throat swab MPXV culture‡	18 (100%)	17 (100%)	1.18 (0.47 – 2.97)	0.73
Negative lesion swab MPXV culture‡	18 (100%)	17 (100%)	1.48 (0.69 – 3.16)	0.31
Subsidiary outcomes				
Clinical status on day 7§	-	-	0.63 (0.17 – 2.36)	0.49
Clinical status on day 14§	-	-	1.09 (0.30 – 4.04)	0.89
Clinical status on day 21§	-	-	0.30 (0.06 – 1.41)	0.13
Clinical status on day 28§	-	-	0.45 (0.07 – 2.83)	0.39
Time to sustained absence of use of analgesia	17 (94%)	17 (100%)	1.01 (0.46 – 2.24)	0.98
Number of patients admitted to hospital for a complication of mpox	0 (0%)	0 (0%)	-	-

Data are n (%). RR=rate ratio (for outcomes of active and complete lesion resolution and absence of analgesia). HR = hazard ratio (for outcomes of throat swab culture). OR = odds ratio (for outcomes of clinical status on days 7, 14, 21 and 28). CI=confidence interval. MPXV = monkeypox virus

* Defined as the first day on which all skin lesions are scabbed or desquamated (and mucosal lesions healed), up to 28 days after randomisation.

† Defined as the first day on which all lesions are completely resolved (all scabs dropped off and intact skin remains underneath, and mucosal lesions healed), up to 28 days after randomisation.

‡ Negative culture on swab taken at days 7, 14, 21, or 28 with no subsequent positive culture.

§ Clinical status on four-point ordinal scale defined in the protocol.

Adverse events

No participants were admitted to hospital during the follow-up period, and no serious adverse events occurred. Three participants stopped taking study treatment because of adverse events; one allocated tecovirimat (reporting headache), and two allocated placebo (one with nausea, the other with nausea, headache and rash).