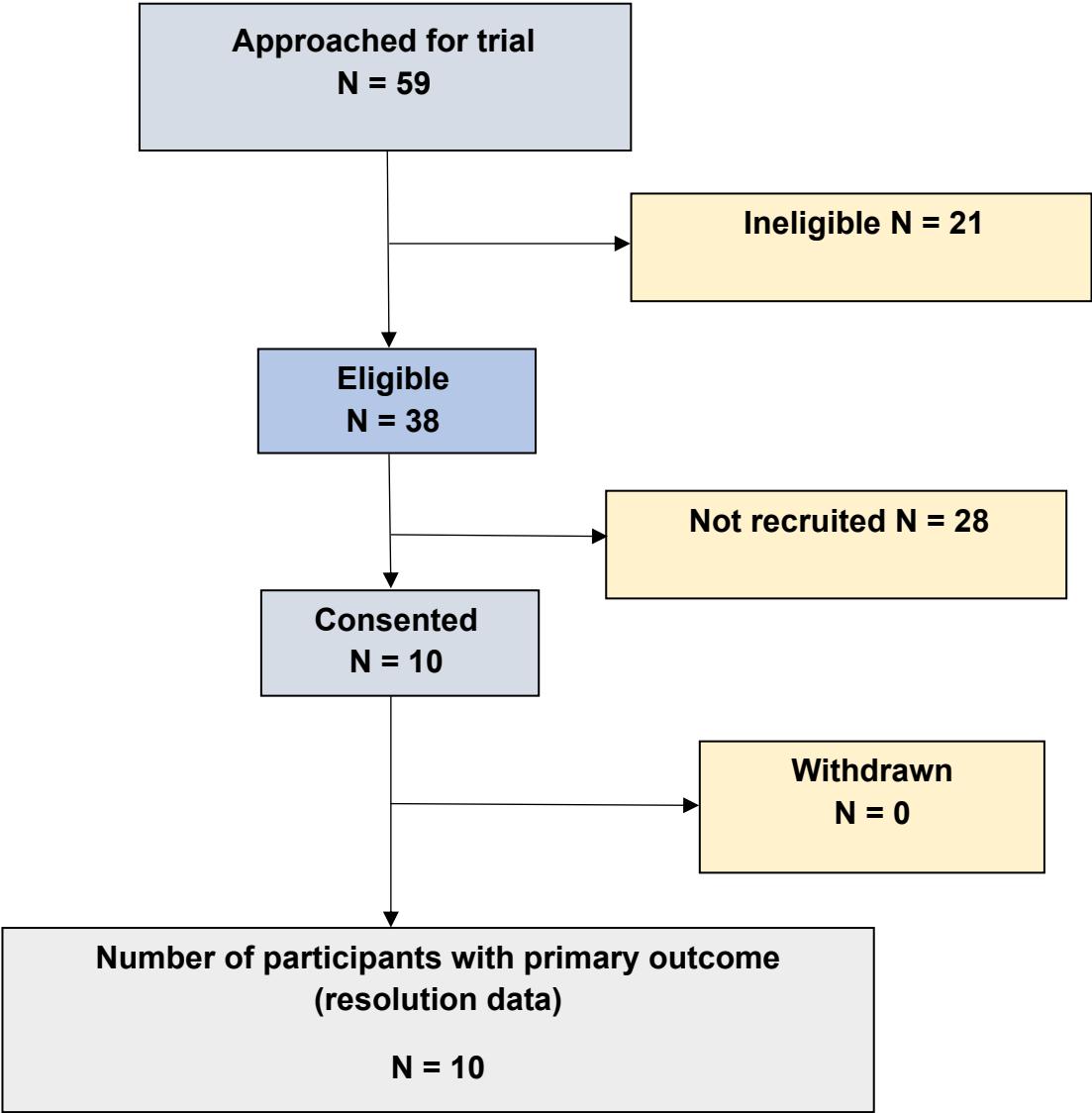


OSPREY Consort diagram



OSPREY Baseline Characteristics

Age	BSA in m2	βhCG
24	1.74	152
27	1.62	160
23	1.48	44
33	1.66	234
36	1.72	809
36	1.72	2299
32	1.7	139
30	1.66	168
27	1.61	1020
39	1.73	434

OSPREY Outcome measures

Primary outcome – effects on blood chemistry (safety)

	CONTROL (n=62)		OSPREY (n=10)		CONTROL (n=62)			OSPREY (n=10)		
	Baseline	Post-MTX	Baseline	Post-MTX	Difference	Percentage	Significance	Difference	Percentage	Significance
Haematology										
Hb (g/L)	132.05 ±1.40	128.85 ±1.10	135.7 ±2.94	131.0 ±2.61	-3.20 ±0.90	-2.42%	P=0.0008***	-4.7 ±1.97	-3.46%	P=0.02*
WCC (10 ⁹ /L)	7.27 ±0.31	6.07 ±0.24	7.11 ±0.42	6.23 ±0.34	-1.20 ±0.23	-16.51%	P<0.0001****	-0.88 ±0.43	-12.38%	P=0.036*
Platelets (10 ⁹ /L)	264.22 ±8.71	249.52 ±7.73	283.3 ±21.25	265.2 ±19.37	-14.70 ±3.38	-5.56%	P<0.0001****	-18.1 ±9.15	-6.39%	P=0.04*
Biochemistry										
Bilirubin (µmol/L)	10.58 ±1.05	9.60 ±0.91	8.40 ±1.17	8.80 ±1.42	-0.98 ±0.53	-9.26%	P=0.069	0.40 ±1.14	4.76%	P=0.733
ALT (IU/L)	16.86 ±1.13	36.61 ±7.90	14.80 ±1.32	28.50 ±7.99	19.75 ±7.69	117.14%	P=0.013*	13.7 ±7.42	92.57%	P=0.049*-3.5-
Alk Phos (IU/L)	60.75 ±2.53	62.48 ±2.44	53.00 ±4.75	50.00 ±4.87	1.73 ±1.43	2.85%	P=0.231	-3.00 ±0.91	-5.66%	P=0.009**

Secondary outcome

In the standard regimen 16.7% of patients required a second dose and in the OSPREY patients 10% required a second dose. In the standard regimen 13% of patients required surgery and in the OSPREY patients 10% needed surgery.

OSPREY Adverse events

Symptom	D4 Control (n=7)	D4 OSPREY (n=10)	D7 Control (n=7)	D7 OSPREY (n=10)
Bloating	1	2=	2	3
Fatigue	2	1	1	1
Flatulence	3	5	3=	4=
Nausea	4	2=	3=	4=
Headache	5	6=	3=	4=
Pain	6=	4	6	2
Loss of Appetite	6=	6=	7	7=
Dizziness	8	8	8=	7=
Mouth Ulcers	9	11=	8=	9=
Diarrhoea	10=	9	10=	9=
Vomiting	10=	10	10=	9=
Rash	12	11=	12	9=