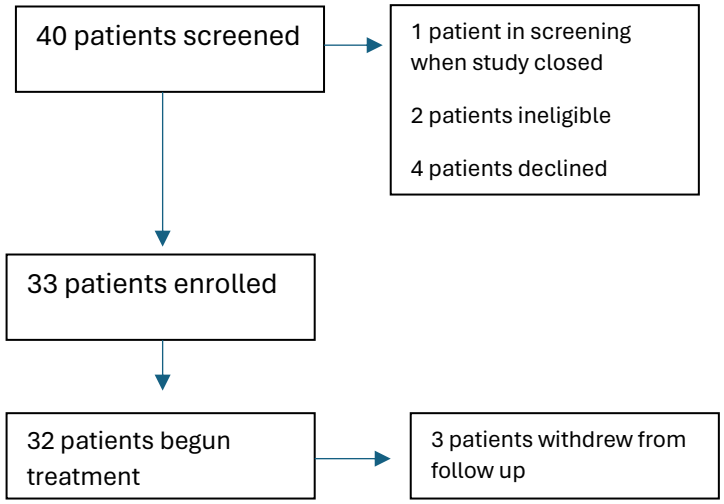
Experience of Rucaparib as Maintenance Treatment following Platinum Based Chemotherapy in Ovarian Cancer – A UK real world study

Results report

Participant flow



Baseline characteristics

Variable	N (nmiss)	Mean (SD)	(Q1) Median (Q3)	Min, Max
Age (years)	33 (1)	67.1 (9.4)	(60) 67 (74)	48, 85
Weight (kg)	32 (1)	72 (12)	(63) 69 (78)	53, 106
Height (cm)	32 (1)	162 (6)	(157) 163 (166)	153, 174
BMI (kg/m^2)	32 (1)	27.1 (4.2)	(24.2) 26.5 (29.9)	20.1, 38.0
SBP (mmHg)	30 (3)	131 (22)	(117) 134 (143)	64, 177
DBP (mmHg)	30 (3)	76 (9)	(71) 76 (82)	52, 91
Charlson comorbidity index (CCI)	33 (1)	6 (3)	(4) 5 (8)	3, 11
CCI ten-year survival probability	33 (1)	29.8 (31.3)	(0.0) 21.4 (53.4)	0.0, 77.5

Ovarian cancer details

Variable	Definition	All consented subjects (N = 34)
Histological subtype	n (missing)	33 (1)
	High grade serious	30 (90.9%)
	High grade endometrioid	1 (3.0%)
	Other	2 (6.1%)

Variable	Definition	All consented subjects (N = 34)
Stage at diagnosis	n (missing)	32 (2)
	1C	2 (6.3%)
	2	3 (9.4%)
	3B	3 (9.4%)
	3C	15 (46.9%)
	4A	5 (15.6%)
	4B	4 (12.5%)
BRCA positive	n (missing)	33 (1)
	Yes	2 (6.1%)

Outcome measure

The primary outcome measures of this study were Adverse Events measured by CTC version 5 and the frequency of dose interruptions and reductions. Please see adverse events section on the following page. The adverse events table also details dose reductions.

Treatment interruptions due to toxicity

Variable	Definition	All interruptions (N = 11, from 9 subject(s))
Reason for interruption	n (missing)	11 (0)
	Adverse event – toxicity	6 (54.5%)
	Adverse event – other	5 (45.5%)
Reason (detail)	n (missing)	2 (9)
	Due to Anaemia	1 (50.0%)
	G2 raised creatinine and G1 hepatic transsaminase rise.	1 (50.0%)
Duration of interruption (days)	n (missing)	11 (0)
	Mean (SD)	20 (15)
	Median (IQR)	21 (8, 25)
	Min, Max	2, 57

Adverse events

Variable	Definition	All AEs (N = 341, from 27 subjects)	Grade 1 (N = 240, from 25 subjects)	Grade 2 (N = 88, from 19 subjects)	Grade 3 (N = 12, from 9 subjects)	Grade 4 (N = 1, from 1 subject)
Description	n (missing)	341 (0)	240 (0)	88 (0)	12 (0)	1 (0)
	Nausea	36 (10.6%)	30 (12.5%)	6 (6.8%)	0	0
	Fatigue	50 (14.7%)	38 (15.8%)	11 (12.5%)	1 (8.3%)	0
	Mucositis	4 (1.2%)	4 (1.7%)	0	0	0
	Allergic reaction	2 (0.6%)	2 (0.8%)	0	0	0
	Vomiting	9 (2.6%)	8 (3.3%)	1 (1.1%)	0	0
	Diarrhoea	8 (2.3%)	2 (0.8%)	6 (6.8%)	0	0
	Neurotoxicity	1 (0.3%)	1 (0.4%)	0	0	0
	Abdominal pain	1 (0.3%)	0	1 (1.1%)	0	0
	Anorexia (loss of appetite)	12 (3.5%)	9 (3.8%)	3 (3.4%)	0	0
	Dysguesia (altered taste)	10 (2.9%)	10 (4.2%)	0	0	0
	Any other adverse events	208 (61.0%)	136 (56.7%)	60 (68.2%)	11 (91.7%)	1 (100.0%)
Number of days experienced since last visit	n (missing)	330 (11)	235 (5)	82 (6)	12 (0)	1 (0)
	Mean (SD)	22 (56)	23 (65)	18 (11)	16 (12)	1 (.)

Variable	Definition	All AEs (N = 341, from 27 subjects)	Grade 1 (N = 240, from 25 subjects)	Grade 2 (N = 88, from 19 subjects)	Grade 3 (N = 12, from 9 subjects)	Grade 4 (N = 1, from 1 subject)
	Median (IQR)	21 (7, 28)	26 (6, 28)	17 (8, 28)	15 (7, 25)	1 (1, 1)
	Min, Max	0, 999	0, 999	0, 38	1, 40	1, 1
Reasonably related to Rucaparib	n (missing)	337 (4)	236 (4)	88 (0)	12 (0)	1 (0)
	Yes	219 (65.0%)	153 (64.8%)	55 (62.5%)	11 (91.7%)	0 (0%)

Serious adverse events

Variable	Definition	All SAEs (N = 11, from 8 subjects)	Grade 2 (N = 5, from 4 subjects)	Grade 3 (N = 4, from 3 subjects)	Grade 4 (N = 1, from 1 subjects)
Days from starting Rucaparib to event	n (missing)	11 (0)	5 (0)	4 (0)	1 (0)
	Mean (SD)	70 (61)	46 (36)	88 (65)	176 (.)
	Median (IQR)	53 (12, 89)	53 (10, 71)	60 (48, 128)	176 (176, 176)
	Min, Max	8, 184	8, 89	47, 184	176, 176
Thought to be related to Rucaparib	n (missing)	11 (0)	5 (0)	4 (0)	1 (0)
	Yes	3 (27.3%)	2 (40.0%)	1 (25.0%)	0 (0%)
CTCAE grade	n (missing)	11 (0)	5 (0)	4 (0)	1 (0)
	Grade 2: Moderate AE	5 (45.5%)	5 (100.0%)	0	0
	Grade 3: Severe AE	4 (36.4%)	0	4 (100.0%)	0
	Grade 4: Life-threatening or disabling AE	1 (9.1%)	0	0	1 (100.0%)
	6	1 (9.1%)	0	0	0
Outcome	n (missing)	11 (0)	5 (0)	4 (0)	1 (0)
	Recovered	6 (54.5%)	3 (60.0%)	3 (75.0%)	0
	Recovered with sequelae	2 (18.2%)	1 (20.0%)	0	1 (100.0%)

Variable	Definition	All SAEs (N = 11, from 8 subjects)	Grade 2 (N = 5, from 4 subjects)	Grade 3 (N = 4, from 3 subjects)	Grade 4 (N = 1, from 1 subjects)
	Recovering	1 (9.1%)	0	0	0
	Not recovered	2 (18.2%)	1 (20.0%)	1 (25.0%)	0
Duration (days) (recovered events only)	n (missing)	6 (0)	3 (0)	3 (0)	0
	Mean (SD)	8 (5)	6 (2)	10 (7)	0
	Median (IQR)	7 (4, 9)	6 (4, 7)	9 (4, 18)	0
	Min, Max	4, 18	4, 7	4, 18	0
Action taken with respect to Rucaparib	n (missing)	11 (0)	5 (0)	4 (0)	1 (0)
	None	2 (18.2%)	0	0	1 (100.0%)
	Dose reduction	1 (9.1%)	1 (20.0%)	0	0
	Treatment interrupted	3 (27.3%)	2 (40.0%)	1 (25.0%)	0
	Treatment stopped	5 (45.5%)	2 (40.0%)	3 (75.0%)	0
If treatment decreased-by how much (%)	n (missing)	1 (0)	1 (0)	0	0
	Mean (SD)	66 (.)	66 (.)	0	0
	Median (IQR)	66 (66, 66)	66 (66, 66)	0	0
	Min, Max	66, 66	66, 66	0	0

Variable	Definition	All SAEs (N = 11, from 8 subjects)	Grade 2 (N = 5, from 4 subjects)	Grade 3 (N = 4, from 3 subjects)	Grade 4 (N = 1, from 1 subjects)
If treatment interrupted- by how many days	n (missing)	3 (0)	2 (0)	1 (0)	0
	Mean (SD)	24 (20)	27 (27)	17 (.)	0
	Median (IQR)	17 (8, 46)	27 (8, 46)	17 (17, 17)	0
	Min, Max	8, 46	8, 46	17, 17	0
Related unexpected SAE (CI assessment)	n (missing)	9 (2)	4 (1)	4 (0)	1 (0)
	Yes	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Related unexpected SAE (PV assessment)	n (missing)	9 (2)	4 (1)	4 (0)	1 (0)
	Yes	0 (0%)	0 (0%)	0 (0%)	0 (0%)