Figure 1 CONSORT diagram of patient disposition

**Note: "Withdrawn" refers to withdrawal from treatment.*

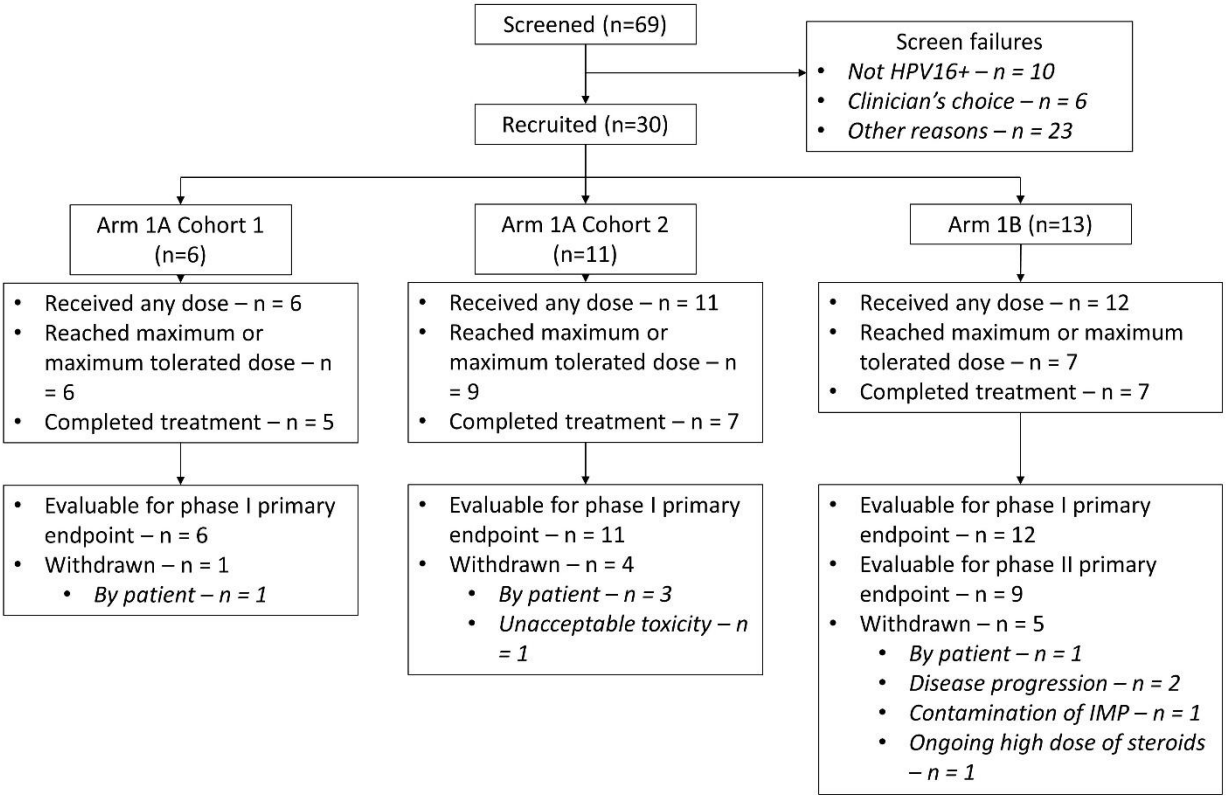


Table 1 Baseline characteristics

Characteristic	Arm 1A (n=17)	Arm 1B (n=13)
Age		
n[1]	17	13
Mean (SD)	61.4 (10.7)	59.3 (7.4)
Median (IQR)	63 (58 to 69)	58 (55 to 67)
Range	37 to 78	49 to 72
Missing from CRF - n (%)[3]	0 (0.0%)	0 (0.0%)
Sex - n (%)[2]		
Male	13 (76.5%)	3 (23.1%)
Female	4 (23.5%)	10 (76.9%)
Other	0 (0.0%)	0 (0.0%)
Missing from CRF - n (%)[3]	0 (0.0%)	0 (0.0%)
Height in cm		
n[1]	17	13
Mean (SD)	172.1 (8.4)	165.4 (8.3)
Median (IQR)	173.5 (169.0 to 176.0)	167.5 (160.0 to 173.0)
Range	151.0 to 184.0	151.0 to 175.0
Missing from CRF - n (%)[3]	0 (0.0%)	0 (0.0%)
Weight in kg		
n[1]	17	12
Mean (SD)	75.9 (14.9)	71.5 (16.5)
Median (IQR)	73.2 (65.9 to 81.2)	70.2 (63.8 to 84.6)
Range	54.6 to 118.3	37.3 to 99.5
Missing from CRF - n (%)[3]	0 (0.0%)	1 (7.7%)
BMI		
n[1]	17	12
Mean (SD)	25.5 (3.4)	26.3 (6.8)
Median (IQR)	24.8 (23.9 to 26.6)	26.0 (21.8 to 28.1)
Range	19.2 to 34.9	16.4 to 42.5
Missing from CRF - n (%)[3]	0 (0.0%)	1 (7.7%)
Primary site of cancer - n (%)[1,3]		
Anal	0 (0.0%)	5 (41.7%)
Cervix	0 (0.0%)	2 (16.7%)
Neck	2 (11.8%)	1 (8.3%)
Oropharynx	3 (17.6%)	1 (8.3%)
Pelvis	0 (0.0%)	1 (8.3%)
Penis	0 (0.0%)	1 (8.3%)
Tongue	5 (29.4%)	1 (8.3%)

Characteristic	Arm 1A (n=17)	Arm 1B (n=13)
Tonsil	7 (41.2%)	0 (0.0%)
Missing from CRF - n (%)[2]	0 (0.0%)	1 (7.7%)
T stage - n (%)[1]		
1	7 (41.2%)	1 (7.7%)
2	7 (41.2%)	2 (15.4%)
3	2 (11.8%)	2 (15.4%)
4a	1 (5.9%)	5 (38.5%)
X	0 (0.0%)	3 (23.1%)
Missing from CRF - n (%)[2]	0 (0.0%)	0 (0.0%)
N stage - n (%)[1]		
0	0 (0.0%)	1 (7.7%)
1	3 (17.6%)	4 (30.8%)
2	2 (11.8%)	1 (7.7%)
2a	1 (5.9%)	1 (7.7%)
2b	7 (41.2%)	1 (7.7%)
2c	4 (23.5%)	1 (7.7%)
3	0 (0.0%)	1 (7.7%)
X	0 (0.0%)	3 (23.1%)
Missing from CRF - n (%)[2]	0 (0.0%)	0 (0.0%)
M stage - n (%)[1]		
0	17 (100.0%)	5 (38.5%)
1	0 (0.0%)	8 (61.5%)
Missing from CRF - n (%)[2]	0 (0.0%)	0 (0.0%)
Systolic blood pressure in mmHg		
n[1]	17	13
Mean (SD)	135.5 (19.6)	133.1 (37.9)
Median (IQR)	138 (129 to 148)	117 (112 to 139)
Range	97 to 179	98 to 248
Missing from CRF - n (%)[3]	0 (0.0%)	0 (0.0%)
Diastolic blood pressure in mmHg		
n[1]	17	13
Mean (SD)	76.9 (11.2)	75.3 (18.0)
Median (IQR)	80 (67 to 85)	74 (63 to 81)
Range	58 to 94	49 to 122
Missing from CRF - n (%)[3]	0 (0.0%)	0 (0.0%)
Resting heart rate in bpm		
n[1]	17	13
Mean (SD)	71.8 (10.5)	85.7 (19.4)

Characteristic	Arm 1A (n=17)	Arm 1B (n=13)
Median (IQR)	68 (63 to 81)	82 (70 to 92)
Range	58 to 90	64 to 125
Missing from CRF - n (%)[3]	0 (0.0%)	0 (0.0%)
Respiratory rate in breaths/min		
n[1]	14	12
Mean (SD)	15.9 (1.5)	16.5 (1.6)
Median (IQR)	16 (16 to 17)	16 (16 to 17.5)
Range	12 to 18	14 to 19
Missing from CRF - n (%)[3]	3 (17.6%)	1 (7.7%)
Temperature (°C)		
n[1]	16	13
Mean (SD)	36.7 (0.6)	36.4 (0.3)
Median (IQR)	36.7 (36.4 to 36.9)	36.2 (36.2 to 36.6)
Range	36.1 to 38.6	36.0 to 36.8
Missing from CRF - n (%)[3]	1 (5.9%)	0 (0.0%)
ECOG - n (%)[2]		
0 = Fully active, able to carry on all pre-disease performance without restriction	15 (88.2%)	3 (25.0%)
1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work	2 (11.8%)	8 (66.7%)
2 = Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours	0 (0.0%)	1 (8.3%)
Missing from CRF - n (%)[3]	0 (0.0%)	1 (7.7%)
ECG - n (%)[2]		
Normal	15 (88.2%)	11 (84.6%)
Sinus bradycardia	2 (11.8%)	0 (0.0%)
Possible anterior MI possibly old	0 (0.0%)	1 (7.7%)
Possible bundle branch block	0 (0.0%)	1 (7.7%)
Missing from CRF - n (%)[3]	0 (0.0%)	0 (0.0%)
LDH (IU/L)		
n[1]	16	13
Mean (SD)	330.1 (44.6)	416.8 (144.0)
Median (IQR)	338 (298.5 to 357)	385 (296 to 473)
Range	240 to 424	260 to 725
Missing from CRF - n (%)[3]	1 (5.9%)	0 (0.0%)

Characteristic	Arm 1A (n=17)	Arm 1B (n=13)
CMV antibodies - n (%)[2]		
Positive	7 (50.0%)	4 (44.4%)
Negative	7 (50.0%)	5 (55.6%)
Missing from CRF - n (%)[3]	3 (17.6%)	4 (30.8%)
CMV IgM- n (%)[2]		
Positive	0 (0.0%)	0 (0.0%)
Negative	12 (100.0%)	9 (100.0%)
Missing from CRF - n (%)[3]	5 (29.4%)	4 (30.8%)
EBV antibodies - n (%)[2]		
Positive	13 (92.9%)	6 (66.7%)
Negative	1 (7.1%)	3 (33.3%)
Missing from CRF - n (%)[3]	3 (17.6%)	4 (30.8%)
EBV IgG - n (%)[2]		
Positive	12 (92.3%)	8 (88.9%)
Negative	1 (7.7%)	1 (11.1%)
Missing from CRF - n (%)[3]	4 (23.5%)	4 (30.8%)
Hep B - n (%)[2]		
No evidence of infection	17 (100.0%)	13 (100.0%)
Evidence of past infection	0 (0.0%)	0 (0.0%)
Missing from CRF - n (%)[3]	0 (0.0%)	0 (0.0%)
Hep C - n (%)[2]		
No evidence of infection	17 (100.0%)	13 (100.0%)
Evidence of past infection	0 (0.0%)	0 (0.0%)
Missing from CRF - n (%)[3]	0 (0.0%)	0 (0.0%)
HIV - n (%)[2]		
Positive	0 (0.0%)	0 (0.0%)
Negative	17 (100.0%)	13 (100.0%)
Missing from CRF - n (%)[3]	0 (0.0%)	0 (0.0%)
P16 - n (%)[2]		
Positive	17 (100.0%)	13 (100.0%)
Negative	0 (0.0%)	0 (0.0%)
Missing from CRF - n (%)[3]	0 (0.0%)	0 (0.0%)
HPV typing - n (%)[2]		
Positive	17 (100.0%)	13 (100.0%)

Characteristic	Arm 1A (n=17)	Arm 1B (n=13)
Negative	0 (0.0%)	0 (0.0%)
Missing from CRF - n (%)[3]	0 (0.0%)	0 (0.0%)
TSH (mU/L)		
n[1]	14	13
Mean (SD)	7.2 (9.6)	6.9 (16.0)
Median (IQR)	4.2 (1.7 to 5.7)	2.1 (1.5 to 3.2)
Range	1.3 to 30.5	0.9 to 60.0
Missing from CRF - n (%)[3]	3 (17.6%)	0 (0.0%)
FT4 (pmol/L)		
n[1]	14	13
Mean (SD)	9.5 (1.6)	12.2 (3.2)
Median (IQR)	9.9 (8.5 to 10.7)	11.2 (10.6 to 15.2)
Range	6.3 to 11.6	5.7 to 17.3
Missing from CRF - n (%)[3]	3 (17.6%)	0 (0.0%)

SD = standard deviation, IQR = inter-quartile range (quartile 1 to quartile 3)

[1] Number of participants who provided non-missing data.

[2] These percentages are calculated using the number of patients in each group with data available.

[3] These percentages are calculated using the number of patients in each group.

Table 2 Dose limiting toxicities (DLT evaluable population)

Characteristic	Arm 1A (n=17)	Arm 1B (n=12)
Number of dose limiting toxicities (DLTs)*	0	0
Patients experiencing a DLT[1] – n (%)	0 (0.0%)	0 (0.0%)
Patients not experiencing a DLT but reached MTD according to the decision of SRC – n (%)	2 (11.8%)	0 (0.0%)
Patients experiencing at least one adverse drug reaction (ADR) that prevented an increase in dose level of vaccination to next dose level – n (%)	0 (0.0%)	1 (8.3%)
Patients experiencing at least one ADR that resulted in reduction to previously tolerated dose level – n (%)	1 (5.9%)	1 (8.3%)
Patients experiencing at least one ADR with intensity of grade 3 or higher – n (%)	4 (23.5%)	3 (25.0%)
Patients experiencing at least one ADR which occurred during or within one week after the vaccination cycle – n (%)	16 (94.1%)	10 (83.3%)
Patients experiencing at least one ADR with outcome neither recovered/resolved nor recovering/resolving within one week – n (%)	9 (52.9%)	4 (33.3%)

*A DLT is defined as an ADR that prevents an increase in dose level of vaccination, which fulfils **all** of the following criteria:

- Intensity of grade 3 or higher,
- Occurrence during or within one week after the vaccination cycle,
- Outcome is neither recovered/resolved nor recovering/resolving within one week.

[1] These statistics or percentages are calculated using the number of patients in each group.

Table 3 Disease control rate at end of treatment according to irRECIST 1.1, Arm 1B (Per protocol population)

Characteristic	Arm 1B (n=9)
No. irRECIST eCRF received, end of treatment – n (%)[1]	8 (88.9%)
Disease response, end of treatment – n (%)[2]	
Complete response	0 (0.0%)
Partial response	0 (0.0%)
Stable disease	5 (62.5%)
Unconfirmed progression	1 (12.5%)
Confirmed progression	1 (12.5%)
Not evaluable	1 (12.5%)
Missing from eCRF – n (%)[1]	1 (11.1%)
Disease control rate, end of treatment – % (95% CI)[2,3]	71.4% (29.0% - 96.3%)

[1] These statistics or percentages are calculated using the number of patients in each group.
[2] These statistics or percentages are calculated using the number of patients in each group with evaluable irRECIST data available.
[3] 95% confidence interval estimated by exact binomial test.