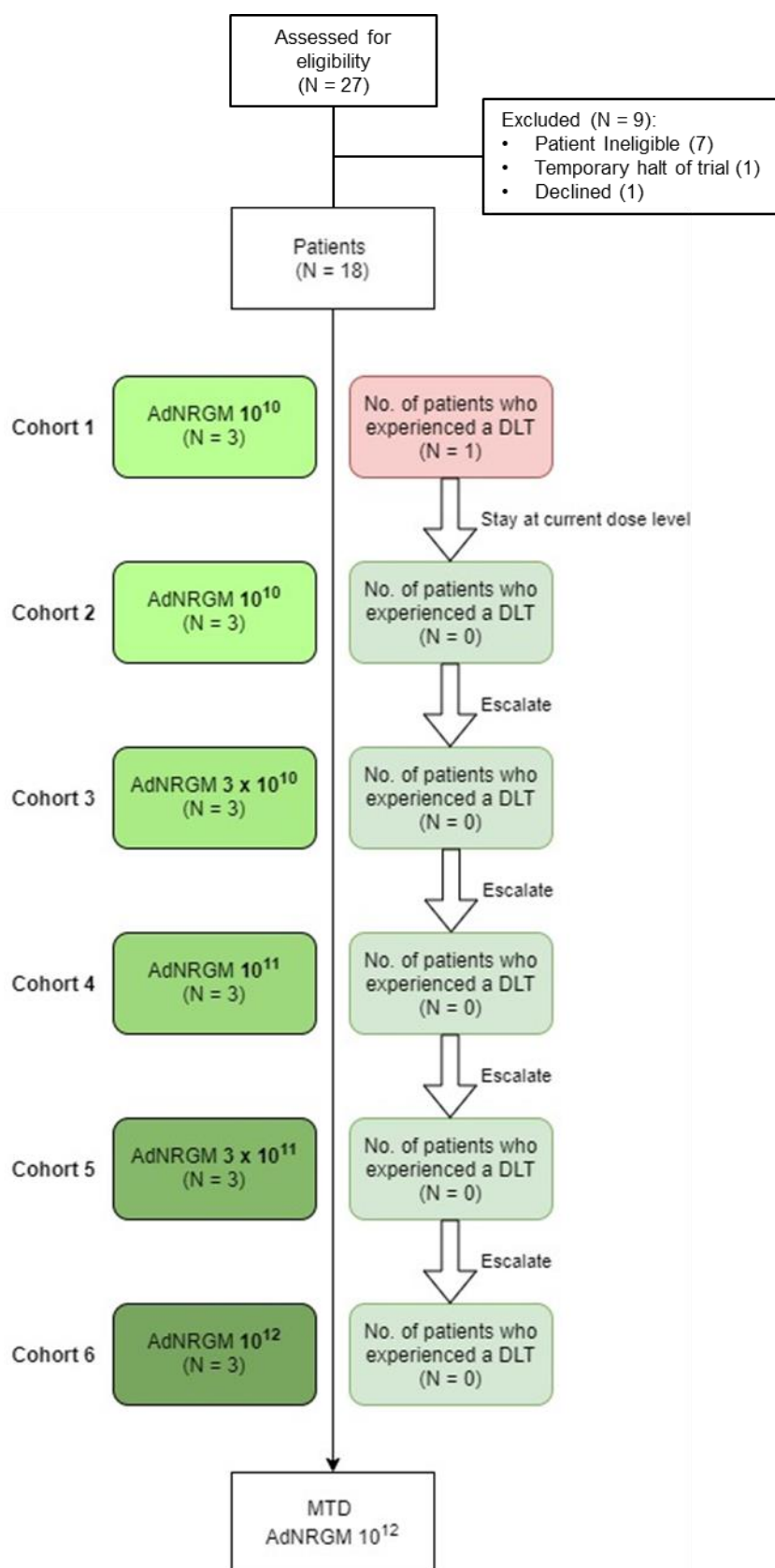


1. Participant Flow



2. Baseline Characteristics

Table 1: Baseline Characteristics

Characteristic		N=18
Sex (N)		
	Male	18
	Female	0
Age (years)		
	N	18
	Median (QR)	71.4 (69.4, 76.5)
	Mean (SD)	72.8 (4.8)
	Range	65.9, 81.2
WHO Performance Status (N)		
	0	17 (94%)
	1	1 (6%)
Histology		
Lobes		
	Both	7(41%)
	Left	4 (24%)
	Right	6 (35%)
	Unknown	1
% Cores positive		
	N	15
	Median (IQR)	25 (10, 67)
	Mean (SD)	37 (32)
	Range	2, 90
	Unknown	3
Total Gleason Score		
	7	7 (41%)
	8	2 (12%)
	9	8 (47%)
	Unknown	1

Characteristic	N=18
Volume of Prostate	
Modality used to calculate volume	
CT	7 (41%)
TRUS	10 (59%)
Unknown	1
Volume (mm³)	
N	18
Median (IQR)	28 (23, 43)
Mean (SD)	34 (13)
Range	20, 58
Last PSA (ng/ml)	
N	18
Median (IQR)	9 (5, 16)
Mean (SD)	12 (9)
Range	3, 29
PSAd (volume/PSA)	
N	17
Median (IQR)	0.30 (0.14, 0.49)
Mean (SD)	0.38 (0.34)
Range	0.05, 1.11
Unknown	1

Characteristic	N=18
Electrocardiogram information	
Heart Rate (bpm)	
N	18
Median (IQR)	66 (59, 69)
Mean (SD)	64 (8)
Range	51, 79
PR (ms)	
N	17
Median (IQR)	192 (176, 211)
Mean	195 (36)
Range	139, 296
Unknown	1
QRS Duration (ms)	
N	18
Median (IQR)	94 (87, 103)
Mean (SD)	99 (20)
Range	73, 148
QT (ms)	
N	18
Median (IQR)	384 (366, 406)
Mean (SD)	370 (83)
Range	49, 428
QTc (ms)	
N	18
Median (IQR)	404 (387, 418)
Mean (SD)	405 (24)
Range	364, 451

3. Outcome Measures

3.1 Primary Outcome

3.1.1 Toxicity, safety and dose limiting toxicities (DLT)

Table 2: Adverse Events - Line Listing of all DLTs

Dose Level	SAE	Toxicity	Category	Grade	Relatedness	Outcome	Duration (days)
1	No	Alanine aminotransferase increased	Investigations	3	Possibly related	Resolved – no sequelae	7
1	No	Aspartate aminotransferase increased	Investigations	3	Possibly related	Resolved – no sequelae	7
1	No	Alanine aminotransferase increased	Investigations	3	Possibly related	Resolved – no sequelae	7

Table 3: DLT rate by Cohort

Cohort	Dose Level	No. of Evaluable Patients	DLT rate
1	1	3	1 (33%)
2	1	3	0 (0%)
3	2	3	0 (0%)
4	3	3	0 (0%)
5	4	3	0 (0%)
6	5	3	0 (0%)

Table 4: DLT rate by Dose Level

Cohort	No. of Evaluable Patients	DLT rate
1	6	1 (17%)
2	3	0 (0%)
3	3	0 (0%)
4	3	0 (0%)
5	3	0 (0%)

Table 5: Line listing of DLT and dose escalation data

Cohort	Dose Level	DLT
1	1	Yes
1	1	No
1	1	No
2	1	No
2	1	No
2	1	No
3	2	No
3	2	No
3	2	No
4	3	No
4	3	No
4	3	No
5	4	No
5	4	No
5	4	No
6	5	No
6	5	No
6	5	No

Each row of the table represents an individual patient.

3.2 Secondary Outcomes

3.2.1 PSA levels and kinetics following treatment with AdNRGM and CB1954

Table 6: Line listing of PSA values collected at later time-points.

Day 0	Day 5	Week 2	Week 3	Week 4	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
11.7	12.4	12.1	12.9	11.8	13.2	16.9	15.2	4.5	19.9	23		25.3	29.7	38.5	43.3
4	4.1	3.3	3.4	3.2	5.5	4.8	5	4.6	6.4	5.9	6.8	6.7	9.7	9.7	12.7
6.4	5	4.5	5.2	5.4	6.2	6.6	7.6	9.8	10.8	12.7		15.8	16.7	17.8	21.8
22.6	20.1	17.8	17.7	17.7		18.7	20.8	20.2	23.2	24.7	20.7	23.4	22.4	32.2	25.9
18.9	17.9	16.4	20.2	18.6	17.8	18.3	20.4	20.2	19.7	23.3	21.2		24.8	22.6	23.6
9.7	11.7	10.6	11.2	11	12.7	15	17.5	23.3	29.6	14.8	11.5	9.7		6.3	5.7
2.4	6.8	6.8	3	2.4	2.7	2.5	2.6	2.3	2.2	2.7	2.2	2	1.9	1.9	2
31.5	35.6	28.5	27.8	25.8	23.8	22.9	24.9	22.7	22.4	23.4	25.2	28.3	31.4		30.5
8.1	8.3	6.2	7.7	8.3	7.7	8.5	8.3	8.9	9.2	10.6	11.9	11.5	12.6	12.8	15.2
10	6.2	3	2.5	2.5	2.2	3.3	4.4	6.1	8.3	10.8	10.5	11.5	12.3	14.2	15.2
74.3	81.4	85.6	87	98.8	137.7	172.5	293.5	361	267	307.5	254.7	153.1	150.6	173.6	296.7
6.2	5.5	5.8	5.9	5.8	5.9	5.9	6.3	7.4	7.3	7.2	6.9	9.1	9.1	8.4	10.1
25.7	11.1	6.5	8.2	9.8	9.1	8.5	8	9.2	10.3	11.1	12.8	13.8	16.5	19.2	24.4
8.2	8.4	7.5	8.7	8.9	8.5	9.8	11.9	13.6	14.6	20.9	21.4	26	28.07	32.6	18
5.7	5.7	5.6	5.5	5.5	5.9	10.5	8.1	11	11.4	11.6	11.6	13.8	13.6	17.6	21.5
4	6.1	2	2.3	2.5	2.8	2.4	2.1	2	2.2	2	2.1	2.1	2.5		2.3
8.3	4.7		4.5	6.1	5.6	6.7	7.6	8.2	8.2	9.6	9.3	10.9			8.3
9.4		9.8	12.1	11.6	15.2	18.7	17.2	17.8	19.5	2.1		0.09			0.01

Each row of the table represents an individual patient.

3.3 Tertiary Outcomes (Exploratory)

3.3.1 Treatment-induced immune responses

Table 7: ELISpot Assay - Summary Statistics at each time point

Characteristic	Baseline, N=18	Week 2, N=18	Week 3, N=18	Week 4, N=18	Month 2, N=18
PSA					
Median (IQR)	-1.7 (-5.0, 3.8)	-0.3 (-2.2, 4.9)	0.0 (-2.7, 3.2)	2.2 (-1.7, 6.7)	0.7 (-2.2, 3.2)
Mean (SD)	-1.6 (6.6)	0.7 (4.9)	1.7 (7.2)	2.3 (5.3)	0.9 (5.1)
Range	-14.7, 9.3	-8.7, 10.0	-6.0, 24.2	-7.3, 12.7	-7.5, 14.6
PAP					
Median (IQR)	2 (-2, 7)	4 (0, 10)	1 (-3, 6)	4 (0, 8)	1 (0, 7)
Mean (SD)	1 (9)	6 (9)	5 (13)	6 (11)	5 (9)
Range	-21, 19	-9, 23	-8, 41	-9, 30	-8, 28
PSMA					
Median (IQR)	0.8 (-0.7, 4.2)	0.0 (-0.5, 1.0)	3.7 (0.7, 6.0)	4.8 (1.0, 6.7)	2.7 (0.7, 6.5)
Mean (SD)	0.1 (6.2)	1.0 (4.0)	4.3 (6.7)	4.0 (6.2)	3.9 (6.8)
Range	-13.3, 8.7	-5.3, 10.0	-4.7, 21.7	-10.7, 16.0	-5.0, 21.7
MAGE-A3					
Median (IQR)	-3.2 (-6.7, 0.7)	-0.7 (-2.5, 0.0)	-1.5 (-4.0, 1.9)	0.2 (-3.6, 6.2)	0.3 (-3.0, 2.4)
Mean (SD)	-3.4 (6.4)	-1.0 (3.2)	0.0 (7.2)	1.0 (7.6)	0.7 (6.6)
Range	-20.0, 6.0	-7.3, 5.3	-10.0, 19.3	-14.7, 16.7	-8.0, 21.7
Unknown	0	1	0	0	0
NYESO/A3/MUC1					
Median (IQR)	8 (3, 14)	4 (-2, 13)	6 (2, 27)	7 (2, 15)	5 (1, 15)
Mean (SD)	18 (41)	12 (26)	20 (36)	23 (40)	18 (33)
Range	-21, 169	-10, 90	-6, 151	-3, 138	-7, 107
Ad5					
Median (IQR)	7 (1, 21)	57 (31, 113)	45 (32, 136)	48 (13, 88)	21 (8, 52)
Mean (SD)	17 (28)	98 (107)	85 (81)	64 (60)	35 (38)
Range	-19, 82	7, 384	5, 255	3, 197	-1, 147
EBNA1/VZVgE					
Median (IQR)	68 (32, 171)	64 (20, 182)	64 (35, 321)	56 (27, 282)	57 (22, 191)
Mean (SD)	176 (252)	170 (246)	171 (198)	171 (206)	169 (249)
Range	2, 987	-2, 954	3, 628	-7, 682	-4, 994

Table 8: ELISA Assay - Summary Statistics at each time point for GM-CSF

Characteristic	Baseline, N = 18	Day 2, N = 18	Day 5-7, N = 18	Week 2, N = 18
GM-CSF				
Median (IQR)	-0.19 (-0.38, -0.12)	4.12 (0.66, 26.44)	1.06 (-0.05, 1.98)	-0.07 (-0.32, 0.34)
Mean (SD)	-0.22 (0.24)	22.52 (38.46)	3.69 (8.93)	0.16 (0.88)
Range	-0.60, 0.33	-0.25, 144.42	-0.48, 37.20	-0.50, 3.40
Unknown	0	0	1	0

4. Adverse Events

Table 9: Adverse events by CTCAE v4.0 category and grade

Adverse Event Category (N (%))	CTCAE Grade	Overall Events (Patients)
Abdominal pain	1	1 (1)
Activated partial thromboplastin time prolonged	1	8 (5)
Acute kidney injury	1	2 (1)
	2	1 (1)
Alanine aminotransferase increased	1	11 (9)
	2	3 (3)
	3	2 (2)
Alkaline phosphatase increased	1	1 (1)
Alopecia	1	1 (1)
Anemia	1	30 (13)
	2	2 (1)
Anorexia	1	6 (6)
	2	1 (1)
Anxiety	2	1 (1)
Aspartate aminotransferase increased	1	7 (7)
	2	1 (1)
	3	1 (1)
Back pain	1	4 (4)
Blood and lymphatic system disorders - Other, specify	1	6 (2)
Blurred vision	1	1 (1)
Cholesterol high	1	1 (1)
Constipation	1	6 (3)
Cough	1	3 (3)
Creatinine increased	1	13 (6)
	2	2 (2)
Dehydration	3	1 (1)
Depression	1	1 (1)
Diarrhea	1	18 (14)
	2	2 (2)
	3	1 (1)
Dizziness	1	1 (1)
Dyspepsia	2	2 (2)
Dyspnea	1	3 (1)
Edema limbs	1	1 (1)
Eye disorders - Other, specify	1	1 (1)

Fatigue	1	9 (9)
	2	2 (2)
Feminization acquired	2	1 (1)
Fever	1	6 (6)
	2	1 (1)
Flu like symptoms	1	12 (8)
	2	1 (1)
Fracture	2	1 (1)
Gastroesophageal reflux disease	1	2 (2)
Gastrointestinal disorders - Other, specify	1	1 (1)
	2	1 (1)
Generalized muscle weakness	1	1 (1)
Genital edema	1	1 (1)
Headache	1	6 (5)
Hematuria	1	5 (4)
	3	2 (1)
Hiccups	1	1 (1)
Hot flashes	1	1 (1)
Hypercalcemia	1	2 (1)
Hyperglycemia	1	2 (1)
Hyperkalemia	1	2 (2)
	2	1 (1)
Hypermagnesemia	1	2 (2)
Hypernatremia	2	1 (1)
Hypertension	1	1 (1)
Hypoalbuminemia	1	2 (2)
Hypocalcemia	1	4 (2)
	2	1 (1)
	3	1 (1)
Hypoglycemia	2	1 (1)
Hypokalemia	1	2 (2)
Hypomagnesemia	3	1 (1)
Hyponatremia	1	1 (1)
Hypophosphatemia	1	6 (3)
	2	9 (8)
Hypoxia	1	1 (1)
Infections and infestations - Other, specify	1	6 (4)
	2	1 (1)

INR increased	1	3 (2)
Investigations - Other, specify	1	111 (17)
	2	1 (1)
Laryngeal inflammation	1	2 (2)
Laryngitis	1	1 (1)
Lower gastrointestinal hemorrhage	1	1 (1)
Lymphocyte count decreased	1	12 (8)
	2	2 (2)
	3	3 (3)
Lymphocyte count increased	1	2 (2)
Metabolism and nutrition disorders - Other, specify	1	8 (3)
Musculoskeletal and connective tissue disorder - Other, specify	1	3 (1)
Myalgia	1	1 (1)
Nail infection	2	1 (1)
Nausea	1	8 (8)
	2	6 (6)
Pain	1	2 (2)
	2	1 (1)
Pelvic pain	1	1 (1)
Penile pain	1	1 (1)
Platelet count decreased	1	11 (6)
Renal and urinary disorders - Other, specify	1	4 (3)
	2	1 (1)
	3	1 (1)
Reproductive system and breast disorders - Other, specify	1	1 (1)
Respiratory, thoracic and mediastinal disorders - Other, specify	1	1 (1)
Sinus bradycardia	1	1 (1)
Skin and subcutaneous tissue disorders - Other, specify	1	3 (2)
Sore throat	1	2 (2)
Stomach pain	1	1 (1)
Urinary frequency	1	4 (4)
Urinary retention	1	1 (1)
	2	2 (2)
	3	1 (1)
Urinary tract infection	2	3 (2)
	3	1 (1)

Urinary tract obstruction	3	1 (1)
Vomiting	1	13 (9)
	2	3 (3)
Weight loss	1	1 (1)
	2	1 (1)
White blood cell decreased	1	6 (4)
Total	All	480 (18)

Table 10: Serious Adverse Events - Number of SAEs by category and Dose Level.

	Dose Level					Overall
	1	2	3	4	5	
Serious Adverse Event Category (N (%))						
Unrelated SAE	1 (17%)	0	5 (83%)	0	0	6
SAR	0	0	0	0	1 (100%)	1
Non-fatal/life-threatening SUSAR	0	0	0	0	0	0
Total	1 (14%)	0	5 (71%)	0	1 (14%)	7