Clinical trial results:
Combination therapy with Nivolumab and PD-L1/IDO peptide vaccine with Montanide to patients with metastatic malignant melanoma

Summary

EudraCT number	2016-004527-23
Trial protocol	DK
Global end of trial date	31 December 2022

Results information

Result version number	v1 (current)
This version publication date	19 January 2023
First version publication date	19 January 2023

Trial information

Trial identification

Sponsor protocol code	MM1636

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03047928
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	National Center for Cancer Immune Therapy
Sponsor organisation address	Borgmester Ib Juuls Vej 25C, 5th floor, Herlev Hospital, Denmark, 2730
Public contact	Trial Executive, National Center for Cancer Immune Therapy (CCIT-DK), inge.marie.svane@regionh.dk
Scientific contact	Trial Executive, National Center for Cancer Immune Therapy (CCIT-DK), cathrine.lund.lorentzen@regionh.dk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 December 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 December 2022
Global end of trial reached?	Yes
Global end of trial date	31 December 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To asses safety and tolerability of combination therapy with Nivolumab and the PD-L1/IDO peptide vaccine with the adjuvant Montanide in patients with metastatic malignant melanoma

Protection of trial subjects:

Trial subjects were evaluated by the PI or another doctor from the CCIT-DK at every appointment regarding the clinical trial.
During the trial period, the patients could call the PI directly if they had any concerns or questions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	7
From 65 to 84 years	22
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

All patients were recruited from Danish oncology centers between 2017-2022.

Pre-assignment

Screening details:

Patients eligible for therapy were screening at Herlev Hospital according to in- and exclusion criteria described in the protocol.

Period 1

Period 1 title	Period 1
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Arm A

Arm description:

Anti PD-1/PD-L1 naïve patients (30 patients). The patient is a candidate for Nivolumab monotherapy. Prior anti-PD-1/anti-PD-L1 antibody treatment is not allowed.

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

3 mg/kg every 14 days for 24 cycles. Patients with ongoing responses could continue nivolumab (6 mg/kg, monthly) for two years or until progressive disease.

Investigational medicinal product name	IDO/PD-L1 vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

IDO/PD-L1 vaccine consisted of:
100 µg of 21-amino-acid peptide sequences from IDO (DTLLKALLEIASCLEKALQVF) and 100 µg of 19-amino-acid peptide sequences from PD-L1 (FMTYWHLLNAFTVTVPKDL)

Number of subjects in period 1	Arm A
Started	30
Completed	30

Period 2

Period 2 title	period 2
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Arm B

Arm description:

Extension cohort. Progressive disease ON anti-PD-1 monotherapy.Subjects should not have experienced serious and/or life-threatening toxicity to antibody therapy.

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

3 mg/kg every 14 days for 24 cycles. Patients with ongoing responses could continue nivolumab (6 mg/kg, monthly) for two years or until progressive disease.

Investigational medicinal product name	IDO/PD-L1 vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

IDO/PD-L1 vaccine consisted of:
100 µg of 21-amino-acid peptide sequences from IDO (DTLLKALLEIASCLEKALQVF) and 100 µg of 19-amino-acid peptide sequences from PD-L1 (FMTYWHLLNAFTVTVPKDL)

Arm title	Arm C

Arm description:

Extension cohort. Progressive disease during follow up OFF anti-PD-1 after clinical benefit (SD/PR/CR) on anti-PD-1 therapy. Subjects should not have discontinued antibody therapy due to serious and/or lifethreatening toxicity.
At the end of trial, four of ten expected patients were included and treated in Arm C.

Arm type	Experimental
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

3 mg/kg every 14 days for 24 cycles. Patients with ongoing responses could continue nivolumab (6 mg/kg, monthly) for two years or until progressive disease.

Investigational medicinal product name	IDO/PD-L1 vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

IDO/PD-L1 vaccine consisted of:
100 µg of 21-amino-acid peptide sequences from IDO (DTLLKALLEIASCLEKALQVF) and 100 µg of 19-amino-acid peptide sequences from PD-L1 (FMTYWHLLNAFTVTVPKDL)

Number of subjects in period 2[1]	Arm B	Arm C
Started	14	4
Completed	10	4
Not completed	4	0
Adverse event, non-fatal	2	-
included in another trial	1	-
Protocol deviation	1	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: The number of subjects in the original cohort (Cohort A) was 30.
Two cohorts (B and C) with ten patients in each cohort were amended

Baseline characteristics

Reporting groups	
Reporting group title	Arm A
Reporting group description:	
Anti PD-1/PD-L1 naïve patients (30 patients). The patient is a candidate for Nivolumab monotherapy. Prior anti-PD-1/anti-PD-L1 antibody treatment is not allowed.	

Reporting group values	Arm A	Total	
Number of subjects	30	30	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	7	7	
From 65-84 years	22	22	
85 years and over	1	1	
Gender categorical Units: Subjects			
Female	14	14	
Male	16	16	

End points

End points reporting groups

Reporting group title	Arm A
Reporting group description:	
Anti PD-1/PD-L1 naïve patients (30 patients). The patient is a candidate for Nivolumab monotherapy. Prior anti-PD-1/anti-PD-L1 antibody treatment is not allowed.	
Reporting group title	Arm B
Reporting group description:	
Extension cohort. Progressive disease ON anti-PD-1 monotherapy.Subjects should not have experienced serious and/or life-threatening toxicity to antibody therapy.	
Reporting group title	Arm C
Reporting group description:	
Extension cohort. Progressive disease during follow up OFF anti-PD-1 after clinical benefit (SD/PR/CR) on anti-PD-1 therapy. Subjects should not have discontinued antibody therapy due to serious and/or lifethreatening toxicity. At the end of trial, four of ten expected patients were included and treated in Arm C.	

Primary: Adverse events

End point title	Adverse events[1]
End point description:	
The primary endpoint is adverse events (AE) assessed by Common Terminology Criteria for Adverse Events (CTCAE) 4.0. The SAEs are listed under "Advderse Events"	
End point type	Primary
End point timeframe:	
December 2017 - December 2022	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There were no statistical analyses specified for this primary end point

End point values	Arm A			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: CTCAE 4.0 (0-5)	30			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

December 2017 - December 2022

Adverse event reporting additional description:

The primary endpoint is adverse events (AE) assessed by Common Terminology Criteria for Adverse Events (CTCAE) 4.0

Assessment type	Systematic

Dictionary used

Dictionary name	CTCAE
Dictionary version	4.0

Reporting groups

Reporting group title	Arm A

Reporting group description:

Anti PD-1/PD-L1 naïve patients (30 patients). The patient is a candidate for Nivolumab monotherapy. Prior anti-PD-1/anti-PD-L1 antibody treatment is not allowed.

Reporting group title	Arm B

Reporting group description:

Extension cohort. Progressive disease ON anti-PD-1 monotherapy.Subjects should not have experienced serious and/or life-threatening toxicity to antibody therapy.

Reporting group title	Arm C

Reporting group description:

Extension cohort. Progressive disease during follow up OFF anti-PD-1 after clinical benefit (SD/PR/CR) on anti-PD-1 therapy. Subjects should not have discontinued antibody therapy due to serious and/or lifethreatening toxicity.
At the end of trial, four of ten expected patients were included and treated in Arm C.

Serious adverse events	Arm A	Arm B	Arm C
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 30 (36.67%)	2 / 14 (14.29%)	1 / 4 (25.00%)
number of deaths (all causes)	12	6	2
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tonsillar disorder	Additional description: Tonsillectomy due to PET positive focus in tonsil. The process was bening.		
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocarditis	Additional description: suspected tretament realted myocarditis		
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0

Nervous system disorders			
Cerebellar embolism	Additional description: due to arterosclerosis		
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Pulmonary embolism			
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis	Additional description: treatment related		
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gallbladder disorder	Additional description: ESWL treatment (had received several ESWL treatments prior to trial therapy)		
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena	Additional description: Suspected melaena. No ulcer was found on gastroscopy. Resolved within a few days.		
subjects affected / exposed	0 / 30 (0.00%)	0 / 14 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis	Additional description: treatment related		
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
pneumonitis			

subjects affected / exposed	2 / 30 (6.67%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 30 (6.67%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency	Additional description: The patient was know with adrenal insufficiency. Admitted with influenza which led to uncontrolled adrenal insufficiency.		
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	1 / 30 (3.33%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Hip fracture			
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Staphylococcal infection	Additional description: Bacteremia.		
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			

subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia	Additional description: e. coli bacterimia (probably caused by a urinary tract infection)		
subjects affected / exposed	0 / 30 (0.00%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Arm A	Arm B	Arm C
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 30 (100.00%)	10 / 14 (71.43%)	4 / 4 (100.00%)
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	17 / 30 (56.67%)	3 / 14 (21.43%)	3 / 4 (75.00%)
occurrences (all)	17	3	3
Infusion related reaction	Additional description: related to nivolumab		
subjects affected / exposed	5 / 30 (16.67%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	5	0	0
Granuloma skin	Additional description: at injection site		
subjects affected / exposed	20 / 30 (66.67%)	5 / 14 (35.71%)	1 / 4 (25.00%)
occurrences (all)	20	5	1
Injection related reaction			
subjects affected / exposed	23 / 30 (76.67%)	4 / 14 (28.57%)	2 / 4 (50.00%)
occurrences (all)	23	4	2
Injection site erythema	Additional description: redness at injection site		

subjects affected / exposed	7 / 30 (23.33%)	1 / 14 (7.14%)	2 / 4 (50.00%)
occurrences (all)	7	1	2
Injection site pruritus	Additional description: pruritus		
subjects affected / exposed	4 / 30 (13.33%)	3 / 14 (21.43%)	1 / 4 (25.00%)
occurrences (all)	4	3	1
Injection site pain	Additional description: pain		
subjects affected / exposed	4 / 30 (13.33%)	0 / 14 (0.00%)	1 / 4 (25.00%)
occurrences (all)	4	0	1
Injection site discomfort	Additional description: myalgia		
subjects affected / exposed	5 / 30 (16.67%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	5	0	0
Ear and labyrinth disorders			
Hearing disability			
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Periorbital oedema			
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dry eye			
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Dry mouth			
subjects affected / exposed	5 / 30 (16.67%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	5	1	0
Nausea			
subjects affected / exposed	8 / 30 (26.67%)	3 / 14 (21.43%)	1 / 4 (25.00%)
occurrences (all)	8	3	1
Stomatitis			
subjects affected / exposed	2 / 30 (6.67%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Alanine aminotransferase increased			
subjects affected / exposed	4 / 30 (13.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	4	4	4
Abdominal pain			

subjects affected / exposed	4 / 30 (13.33%)	2 / 14 (14.29%)	1 / 4 (25.00%)
occurrences (all)	4	2	1
colitis			
subjects affected / exposed	3 / 30 (10.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Constipation			
subjects affected / exposed	2 / 30 (6.67%)	1 / 14 (7.14%)	1 / 4 (25.00%)
occurrences (all)	2	1	1
Diarrhoea			
subjects affected / exposed	9 / 30 (30.00%)	2 / 14 (14.29%)	1 / 4 (25.00%)
occurrences (all)	9	2	1
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	7 / 30 (23.33%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	7	1	0
Pleural effusion			
subjects affected / exposed	1 / 30 (3.33%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Pneumonitis			
subjects affected / exposed	3 / 30 (10.00%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	3	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	8 / 30 (26.67%)	2 / 14 (14.29%)	0 / 4 (0.00%)
occurrences (all)	8	5	0
Vitiligo			
subjects affected / exposed	4 / 30 (13.33%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	4	1	0
Rash maculo-papular			
subjects affected / exposed	16 / 30 (53.33%)	1 / 14 (7.14%)	1 / 4 (25.00%)
occurrences (all)	16	1	1
Dry skin			
subjects affected / exposed	8 / 30 (26.67%)	3 / 14 (21.43%)	1 / 4 (25.00%)
occurrences (all)	8	3	1
Endocrine disorders			

Hyponatraemia			
subjects affected / exposed	1 / 30 (3.33%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Amylase increased			
subjects affected / exposed	6 / 30 (20.00%)	2 / 14 (14.29%)	0 / 4 (0.00%)
occurrences (all)	6	2	0
Hypophysitis			
subjects affected / exposed	2 / 30 (6.67%)	1 / 14 (7.14%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Hyperthyroidism			
subjects affected / exposed	2 / 30 (6.67%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Hypothyroidism			
subjects affected / exposed	1 / 30 (3.33%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Adrenal insufficiency			
subjects affected / exposed	2 / 30 (6.67%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	5 / 30 (16.67%)	0 / 14 (0.00%)	0 / 4 (0.00%)
occurrences (all)	5	0	0
Arthralgia			
subjects affected / exposed	11 / 30 (36.67%)	0 / 14 (0.00%)	1 / 4 (25.00%)
occurrences (all)	11	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 September 2018	Two new patient cohorts were added to the trial: Cohort B: Extension cohort (10 patients). Progressive disease ON anti-PD-1 monotherapy.Subjects should not have experienced serious and/or life-threatening toxicity to antibody therapy. Cohort C: Extension cohort (10 patients). Progressive disease during follow up OFF anti-PD-1 after clinical benefit (SD/PR/CR) on anti-PD-1 therapy. Subjects should not have discontinued antibody therapy due to serious and/or lifethreatening toxicity

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/34887574