Study Results

Participant Flow

Recruitment Details	At enrollment patients was randomized to receive Late (II) vs Early (I) treatment and Pom-Cyclo-dex (B) vs Pom-dex (A) at the same time. If patient was randomized to receive I treatment, the result of the comparison between BvsA was immediately available. Otherwise, in case of II treatment the random disclosure of the comparison between B vs A arm was at the confirmation of CRAB. Patients was randomized using blocks of sizes 12 by the electronic Case Report Form.
Pre-assignment Details	For previous reason 1pt randomized to Late (II) treatment who not achieved a CRAB has not the disclosure of the randomization between A vs B arm.

Reporting Groups

	Description
ARM Pom-dex Early (A-I)	Patients will receive treatment at biochemical relapse with pom-dex Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance
ARM Pom-dex Late (A-II)	Patients will be randomized at biochemical relapse and they will start treatment with pom-dex at the onset of CRAB symptoms/significant paraprotein increase. Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance
ARM Pom-cyclo-dex Early (B-I)	Patients will receive treatment at biochemical relapse with pom-cyclo-dex Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Cyclophosphamide: 50 mg every other day as oral administration (PO) on days 1-28 Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance
ARM Pom-cyclo-dex Late (B-II)	Patients will be randomized at biochemical relapse and they will start treatment with pom-cyclo-dex at the onset of CRAB symptoms/significant paraprotein increase. Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Cyclophosphamide: 50 mg every other day as oral administration (PO) on days 1-28 Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance

Overall Study

	ARM Pom-dex Early (A-I)	ARM Pom-dex Late (A-II)	ARM Pom-cyclo-dex Early (B-I)	ARM Pom-cyclo-dex Late (B-II)
Started	3	1	2	2
Completed [1]	0	0	0	0

	ARM Pom-dex Early (A-I)	ARM Pom-dex Late (A-II)	ARM Pom-cyclo-dex Early (B-I)	ARM Pom-cyclo-dex Late (B-II)
Not Completed	3	1	2	2
Adverse Event	0	0	1	0
PD	2	1	1	1
Withdrawal by Subject	1	0	0	0
Closed study by sponsor	0	0	0	1

[1] Treatment is continous until progression disease (PD), so treatment has not a specific duration and so "completed" is Not Applicable.

Baseline Characteristics

Baseline Analysis Population Description

This analysis included only patients in whom CPd vs Pd randomization was disclosed; 1pt randomized to Late (II) treatment who not achieved a CRAB has not the disclosure of the randomization between A vs B arm..

Reporting Groups

	Description
ARM Pom-dex Early (A-I)	Patients will receive treatment at biochemical relapse with pom-dex Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance
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ARM Pom-cyclo-dex Early (B-I)	Patients will receive treatment at biochemical relapse with pom-cyclo-dex Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Cyclophosphamide: 50 mg every other day as oral administration (PO) on days 1-28 Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance
ARM Pom-cyclo-dex Late (B-II)	Patients will be randomized at biochemical relapse and they will start treatment with pom-cyclo-dex at the onset of CRAB symptoms/significant paraprotein increase. Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Cyclophosphamide: 50 mg every other day as oral administration (PO) on days 1-28 Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance

Baseline Measures

		ARM Pom-dex Early (A-I)	ARM Pom-dex Late (A-II)	ARM Pom-cyclo-dex Early (B-I)	ARM Pom-cyclo-dex Late (B-II)	Total
Overall Number of Participants		3	1	2	2	8
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	3 participants	1 participants	2 participants	2 participants	8 participants
	<=18 years	0 0%	0 0%	0 0%	0 0%	0 0%
	Between 18 and 65 years	2 66.67%	0 0%	1 50%	2 100%	5 62.5%
	>=65 years	1 33.33%	1 100%	1 50%	0 0%	3 37.5%
Age, Continuous Median (Full Range) Unit of measure: years	Number Analyzed	3 participants	1 participants	2 participants	2 participants	8 participants
		54 (43 to 79)	68 (68 to 68)	59.5 (52 to 67)	60 (60 to 60)	60 (43 to 79)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	3 participants	1 participants	2 participants	2 participants	8 participants
	Female	1 33.33%	0 0%	1 50%	0 0%	2 25%
	Male	2 66.67%	1 100%	1 50%	2 100%	6 75%
Race/Ethnicity, Customized Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	3 participants	1 participants	2 participants	2 participants	8 participants
Caucasian		3 100%	1 100%	2 100%	2 100%	8 100%
Region of Enrollment Measure Type: Number Unit of measure: participants	Number Analyzed	3 participants	1 participants	2 participants	2 participants	8 participants
Italy		3	1	2	2	8

		ARM Pom-dex Early (A-I)	ARM Pom-dex Late (A-II)	ARM Pom-cyclo-dex Early (B-I)	ARM Pom-cyclo-dex Late (B-II)	Total
Eastern Cooperative Oncology Group (ECOG) Performance Status [1] Measure Type: Number Unit of measure: participants	Number Analyzed	3 participants	1 participants	2 participants	2 participants	8 participants
0		2	0	1	2	5
1		1	1	1	0	3
		[1] Measure Description: ECOG 0-5; the best is 0, 5 is death				
isotype Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	3 participants	1 participants	2 participants	2 participants	8 participants
IgG		3 100%	0 0%	2 100%	2 100%	7 87.5%
Bj		0 0%	1 100%	0 0%	0 0%	1 12.5%
International Staging System (ISS) Stage [1] Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	3 participants	1 participants	2 participants	2 participants	8 participants
I		2 66.67%	0 0%	2 100%	2 100%	6 75%
II		1 33.33%	1 100%	0 0%	0 0%	2 25%
		[1] Measure Description: International Staging System (ISS) for Multiple Myeloma Stage VALUES (β2M = Serum β2 microglobulin; ALB = serum albumin I β2M < 3.5 mg/L; ALB ≥ 3.5 g/dL II β2M < 3.5 mg/L; ALB ≥ 3.5 g/dL; or β2M 3.5 – 5.5 mg/L III β2M > 5.5 mg/L I low risk, II medium risk, III high risk				

		ARM Pom-dex Early (A-I)	ARM Pom-dex Late (A-II)	ARM Pom-cyclo-dex Early (B-I)	ARM Pom-cyclo-dex Late (B-II)	Total
Previous Therapies (induction/ Autologous Stem Cell Transplantation/ consolidation) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	3 participants	1 participants	2 participants	2 participants	8 participants
ASCT		2 66.67%	1 100%	2 100%	2 100%	7 87.5%
Len		3 100%	0 0%	2 100%	2 100%	7 87.5%
Bort		2 66.67%	0 0%	2 100%	0 0%	4 50%

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Overall Survival (OS)
Measure Description	defined as the time from the date of random disclosure to the date of death from any cause for the comparisons B vs A
Time Frame	57 months

Analysis Population Description

This analysis included only patients in whom CPd vs Pd randomization was disclosed.

Reporting Groups

	Description
Arm A	Pd
Arm B	CPd

Measured Values

	Arm A	Arm B
Overall Number of Participants Analyzed	4	4

	Arm A	Arm B
Overall Survival (OS) Measure Type: Count of Participants Unit of measure: participants		
Death	2 50%	0 0%
Censored	2 50%	4 100%

2. Primary Outcome Measure:

Measure Title	Overall Survival
Measure Description	defined as the time from the date of random disclosure to the date of death from any cause for the comparisons II vs I
Time Frame	57 months

Analysis Population Description

This analysis included only patients in whom CPd vs Pd randomization was disclosed.

Reporting Groups

	Description
Arm I	Early Treatment
Arm II	Late treatment

Measured Values

		Arm I	Arm II
Overall Number of Participants Analyzed		5	3
Overall Survival Measure Type: Count of Participants Unit of measure: participants	Death	1 20%	1 33.33%
	Censored	4 80%	2 66.67%

3. Secondary Outcome Measure:

Measure Title	Clinical Progression

Measure Description	defined as the time from random assignment to the early or late strategy to the date of onset of CRAB symptoms or death. Clinical relapse requires one or more direct indicators of progressive disease and end organ dysfunction (CRAB features). Evidence of end organ damage that can be attributed to the underlying plasma cell proliferative disorder: • hypercalcaemia • renal insufficiency • anaemia • bone lesions Any one or more of the following biomarkers of malignancy: • clonal bone marrow plasma cell percentage ≥60% • involved:uninvolved serum free light chain ratio ≥100 • >1 focal lesions on MRI studies (each focal lesion must be 5 mm or more in size) Progresson was defined accoring to IMWG criteria as reported before
Time Frame	57 months

Analysis Population Description

All population

Reporting Groups

	Description
Arm I	Early Treatment
Arm II	Late treatment

Measured Values

		Arm I	Arm II
Overall Number of Participants Analyzed		5	4
Clinical Progression Measure Type: Count of Participants Unit of measure: participants	Not evaluable	5 100%	3 75%
	Without CRAB	0 0%	1 25%

4. Secondary Outcome Measure:

Measure Title	Progression Free-survival (PFS)

Measure Description	PFS for the comparison B vs A will be measured from the date of randomization disclosure to the date of first observation of PD, or death from any cause as an event. Subjects who have not progressed or who withdraw from the study will be censored at the time of the last complete disease assessment. All subjects who were lost to Follow Up (FU) will also be censored at the time of last complete disease assessment
Time Frame	57 months

Analysis Population Description
ITT

Reporting Groups

	Description
Arm A	Pd
Arm B	CPd

Measured Values

		Arm A	Arm B
Overall Number of Participants Analyzed		4	4
Progression Free-survival (PFS) Measure Type: Count of Participants Unit of measure: participants	Events	3 75%	1 25%
	Censored	1 25%	3 75%

5. Secondary Outcome Measure:

Measure Title	Progression Free Survival (PFS)
Measure Description	PFS for the comparison II vs I will be measured from the date of randomization disclosure to the date of first observation of PD, or death from any cause as an event. Subjects who have not progressed or who withdraw from the study will be censored at the time of the last complete disease assessment. All subjects who were lost to FU will also be censored at the time of last complete disease assessment
Time Frame	57 months

Analysis Population Description
This analysis included only patients in whom CPd vs Pd randomization was disclosed.

Reporting Groups

	Description
Arm I	Early Treatment
Arm II	Late treatment

Measured Values

		Arm I	Arm II
Overall Number of Participants Analyzed		5	3
Progression Free Survival (PFS) Measure Type: Count of Participants Unit of measure: participants	Events	3 60%	1 33.33%
	Censored	2 40%	2 66.67%

6. Secondary Outcome Measure:

Measure Title	Progression Free-survival 2(PFS2)
Measure Description	PFS for the comparison B vs A will be measured from the date of randomization disclosure to the date of first observation of PD in second line therapy, or death from any cause as an event. Subjects who have not progressed or who withdraw from the study will be censored at the time of the last complete disease assessment. All subjects who were lost to FU will also be censored at the time of last complete disease assessment
Time Frame	57 months

Analysis Population Description

ITT

Reporting Groups

	Description
Arm A	Pd
Arm B	CPd

Measured Values

	Arm A	Arm B
Overall Number of Participants Analyzed	4	4

		Arm A	Arm B
Progression Free-survival 2(PFS2) Measure Type: Count of Participants Unit of measure: participants	Events	2 50%	1 25%
	Censored	2 50%	3 75%

7. Secondary Outcome Measure:

Measure Title	Progression Free Survival 2(PFS2)
Measure Description	PFS for the comparison II vs I will be measured from the date of randomization disclosure to the date of first observation of PD in second line therapy, or death from any cause as an event. Subjects who have not progressed or who withdraw from the study will be censored at the time of the last complete disease assessment. All subjects who were lost to FU will also be censored at the time of last complete disease assessment
Time Frame	57 months

Analysis Population Description

This analysis included only patients in whom CPd vs Pd randomization was disclosed.

Reporting Groups

	Description
Arm I	Early Treatment
Arm II	Late treatment

Measured Values

		Arm I	Arm II
Overall Number of Participants Analyzed		5	3
Progression Free Survival 2(PFS2) Measure Type: Count of Participants Unit of measure: participants	Events	2 40%	1 33.33%
	Censored	3 60%	2 66.67%

8. Secondary Outcome Measure:

Measure Title	Objective Overall Response Rate for the Comparison B vs A
Measure Description	in terms of partial response (PR), very good partial response (VGPR), complete response (CR).and stringent complete response (sCR) according to IMWG response crieria (https://www.myeloma.org/resource-library/international-myeloma-working-group-imwg-uniform-response-criteria-multiple).
Time Frame	57 months

Analysis Population Description

ITT

Reporting Groups

	Description
Arm A	Pd
Arm B	CPd

Measured Values

		Arm A	Arm B
Overall Number of Participants Analyzed		4	4
Objective Overall Response Rate for the Comparison B vs A Measure Type: Count of Participants Unit of measure: participants	sCR	0 0%	0 0%
	CR	0 0%	0 0%
	VGPR	0 0%	0 0%
	PR	0 0%	3 75%
	SD	2 50%	0 0%
	PD	1 25%	1 25%
	NE	1 25%	0 0%

9. Secondary Outcome Measure:

Measure Title	Objective Overall Response Rate for the Comparison II vs I
Measure Description	in terms of partial response (PR), very good partial response (VGPR), complete response (CR).and stringent complete response (sCR) according to IMWG response crieria (https://www.myeloma.org/resource-library/international-myeloma-working-group-imwg-uniform-response-criteria-multiple).
Time Frame	57 months

Analysis Population Description
ITT

Reporting Groups

	Description
Arm I	Early Treatment
Arm II	Late Treatment

Measured Values

		Arm I	Arm II
Overall Number of Participants Analyzed		5	3
Objective Overall Response Rate for the Comparison II vs I Measure Type: Count of Participants Unit of measure: participants	sCR	0 0%	0 0%
	CR	0 0%	0 0%
	VGPR	0 0%	0 0%
	PR	1 20%	2 66.67%
	SD	2 40%	0 0%
	PD	1 20%	1 33.33%
	NE	1 20%	0 0%

10. Secondary Outcome Measure:

Measure Title	Quality of Life Questionnaire (QLQ) With EORTC-QLQ-C30
Measure Description	outcome will be measured with EORTC-QLQ-C30 at baseline, every 2 months during the first year, and then every 6 months for the comparison B vs B and I vs II.
Time Frame	57 months

Analysis Population Description
data could not be reported in the data table since analysis was not performed according to the lower sample size and QLQ missing

Reporting Groups

	Description
ARM A-I	Patients will receive treatment at biochemical relapse with pom-dex Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance

	Description
ARM A-II	Patients will be randomized at biochemical relapse and they will start treatment with pom-dex at the onset of CRAB symptoms/significant paraprotein increase. Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance
ARM B-I	Patients will receive treatment at biochemical relapse with pom-cyclo-dex Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Cyclophosphamide: 50 mg every other day as oral administration (PO) on days 1-28 Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance
ARM B-II	Patients will be randomized at biochemical relapse and they will start treatment with pom-cyclo-dex at the onset of CRAB symptoms/significant paraprotein increase. Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Cyclophosphamide: 50 mg every other day as oral administration (PO) on days 1-28 Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance

Measured Values

	ARM A-I	ARM A-II	ARM B-I	ARM B-II
Overall Number of Participants Analyzed	0	0	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

11. Secondary Outcome Measure:

Measure Title	Quality of Life With QLQ-MY(Myeloma)24
Measure Description	outcome will be measured with QLQ-MY24 at baseline, every 2 months during the first year, and then every 6 months for the comparison B vs B and I vs II.
Time Frame	57 months

Analysis Population Description

data could not be reported in the data table since analysis was not performed according to the lower sample size and QLQ missing

Reporting Groups

	Description
ARM A-I	Patients will receive treatment at biochemical relapse with pom-dex Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance

	Description
ARM A-II	Patients will be randomized at biochemical relapse and they will start treatment with pom-dex at the onset of CRAB symptoms/significant paraprotein increase. Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance
ARM B-I	Patients will receive treatment at biochemical relapse with pom-cyclo-dex Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Cyclophosphamide: 50 mg every other day as oral administration (PO) on days 1-28 Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance
ARM B-II	Patients will be randomized at biochemical relapse and they will start treatment with pom-cyclo-dex at the onset of CRAB symptoms/significant paraprotein increase. Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Cyclophosphamide: 50 mg every other day as oral administration (PO) on days 1-28 Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance

Measured Values

	ARM A-I	ARM A-II	ARM B-I	ARM B-II
Overall Number of Participants Analyzed	0	0	0	0

No data displayed because Outcome Measure has zero total participants analyzed.

Reported Adverse Events

Time Frame	from randomization through study completion, up to 57 months, an average of 45 months
Adverse Event Reporting Description	In the table "Other Adverse Events" each term reports ae term_ctcae grade

Reporting Groups

	Description
ARM Pom-dex Early (A-I)	Patients will receive treatment at biochemical relapse with pom-dex Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance
ARM Pom-dex Late (A-II)	Patients will be randomized at biochemical relapse and they will start treatment with pom-dex at the onset of CRAB symptoms/significant paraprotein increase. Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance

	Description
ARM Pom-cyclo-dex Early (B-I)	Patients will receive treatment at biochemical relapse with pom-cyclo-dex Pomalidomide: 4 mg/daily as oral administration (PO) on days 1-21. Cyclophosphamide: 50 mg every other day as oral administration (PO) on days 1-28 Dexamethasone: 40 mg as oral administration (PO) on days 1, 8, 15, 22. For 28-day cycles until progression or intolerance
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All-Cause Mortality

	ARM Pom-dex Early (A-I)		ARM Pom-dex Late (A-II)		ARM Pom-cyclo-dex Early (B-I)		ARM Pom-cyclo-dex Late (B-II)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total All-Cause Mortality	1/3 (33.33%)		1/1 (100%)		0/2 (0%)		0/2 (0%)	

Serious Adverse Events

	ARM Pom-dex Early (A-I)		ARM Pom-dex Late (A-II)		ARM Pom-cyclo-dex Early (B-I)		ARM Pom-cyclo-dex Late (B-II)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	1/3 (33.33%)		0/1 (0%)		0/2 (0%)		0/2 (0%)	
Renal and urinary disorders								
Acute renal failure †	1/3 (33.33%)	1	0/1 (0%)	0	0/2 (0%)	0	0/2 (0%)	0

† Indicates events were collected by systematic assessment.

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	ARM Pom-dex Early (A-I)		ARM Pom-dex Late (A-II)		ARM Pom-cyclo-dex Early (B-I)		ARM Pom-cyclo-dex Late (B-II)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Total	2/3 (66.67%)		1/1 (100%)		1/2 (50%)		2/2 (100%)	
Blood and lymphatic system disorders								
Anemia_1 †	1/3 (33.33%)	1	0/1 (0%)	0	0/2 (0%)	0	0/2 (0%)	0
Neutropenia_3 †	1/3 (33.33%)	1	1/1 (100%)	1	1/2 (50%)	5	0/2 (0%)	0
Thrombocytopenia_1 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
Cardiac disorders								
Sinus tachycardia_3 †	0/3 (0%)	0	0/1 (0%)	0	0/2 (0%)	0	1/2 (50%)	1
Gastrointestinal disorders								
Constipation_1 †	0/3 (0%)	0	1/1 (100%)	1	0/2 (0%)	0	0/2 (0%)	0
Diarrhea_2 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
Vomiting_2 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
General disorders								
Chills_1 †	0/3 (0%)	0	1/1 (100%)	1	0/2 (0%)	0	0/2 (0%)	0
Fatigue_1 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
Fatigue_2 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	1/2 (50%)	1
Fatigue_3 †	0/3 (0%)	0	1/1 (100%)	1	1/2 (50%)	1	1/2 (50%)	1
Fever_3 †	0/3 (0%)	0	0/1 (0%)	0	0/2 (0%)	0	1/2 (50%)	1
Flu like symptoms_2 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	1/2 (50%)	1
Infections and infestations								
Bronchial infection_2 †	1/3 (33.33%)	1	0/1 (0%)	0	0/2 (0%)	0	1/2 (50%)	1

	ARM Pom-dex Early (A-I)		ARM Pom-dex Late (A-II)		ARM Pom-cyclo-dex Early (B-I)		ARM Pom-cyclo-dex Late (B-II)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Gastroenteritis_1 †	0/3 (0%)	0	0/1 (0%)	0	0/2 (0%)	0	1/2 (50%)	1
Gastroenteritis_2 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
Lung infection_2 †	1/3 (33.33%)	1	0/1 (0%)	0	0/2 (0%)	0	0/2 (0%)	0
Upper respiratory tract infection_2 †	1/3 (33.33%)	1	0/1 (0%)	0	0/2 (0%)	0	1/2 (50%)	1
Injury, poisoning and procedural complications								
Eye burns_2 †	1/3 (33.33%)	1	0/1 (0%)	0	0/2 (0%)	0	0/2 (0%)	0
Traumatic ulcer_3 †	0/3 (0%)	0	0/1 (0%)	0	0/2 (0%)	0	1/2 (50%)	1
Investigations								
ALT increased_2 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
AST increased_1 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
Metabolism and nutrition disorders								
Hyperglycemia_2 †	0/3 (0%)	0	0/1 (0%)	0	0/2 (0%)	0	1/2 (50%)	1
Musculoskeletal and connective tissue disorders								
Muscle cramps_1 †	0/3 (0%)	0	0/1 (0%)	0	0/2 (0%)	0	1/2 (50%)	1
Muscle cramps_3 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
Muscle weakness_3 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
Pain in limb_1 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
Pain in limb_2 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
Pain in limb_3 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
Nervous system disorders								
Peripheral motor neuropathy_2 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
Presyncope_2 †	0/3 (0%)	0	0/1 (0%)	0	0/2 (0%)	0	1/2 (50%)	1
Somnolence_2 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
Psychiatric disorders								

	ARM Pom-dex Early (A-I)		ARM Pom-dex Late (A-II)		ARM Pom-cyclo-dex Early (B-I)		ARM Pom-cyclo-dex Late (B-II)	
	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events	Affected/ At Risk (%)	# Events
Agitation_1 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
Agitation_2 †	1/3 (33.33%)	1	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
Agitation_3 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	1/2 (50%)	1
Confusion_2 †	1/3 (33.33%)	1	0/1 (0%)	0	0/2 (0%)	0	0/2 (0%)	0
Insomnia_2 †	1/3 (33.33%)	1	0/1 (0%)	0	0/2 (0%)	0	0/2 (0%)	0
Respiratory, thoracic and mediastinal disorders								
Lung nodule_3 †	1/3 (33.33%)	1	0/1 (0%)	0	0/2 (0%)	0	0/2 (0%)	0
Skin and subcutaneous tissue disorders								
Erythema multiforme_2 †	0/3 (0%)	0	0/1 (0%)	0	0/2 (0%)	0	1/2 (50%)	1
Leg ulcer_2 †	0/3 (0%)	0	0/1 (0%)	0	1/2 (50%)	1	0/2 (0%)	0
Rash maculo-papular_2 †	2/3 (66.67%)	2	0/1 (0%)	0	0/2 (0%)	0	0/2 (0%)	0
Vascular disorders								
Hypertension_1 †	0/3 (0%)	0	0/1 (0%)	0	0/2 (0%)	0	1/2 (50%)	1
Superficial thrombophlebitis_2 †	0/3 (0%)	0	0/1 (0%)	0	0/2 (0%)	0	1/2 (50%)	1

† Indicates events were collected by systematic assessment.

Limitations and Caveats

Main limitations is that the sample size of participants needed to achieve target power and statistically reliable results was not reach. And no statistical testing was performed.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

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