Trial record **6 of 77** for: Interferon alfa-2b AND interferon alfa-2b AND Intron A | Melanoma

Previous Study | Return to List | Next Study

Temozolomide Alone or With Pegylated Interferon-Alpha 2b (PGI) in Melanoma Patients

ClinicalTrials.gov Identifier: NCT00525031

Recruitment Status : Completed
First Posted : September 5, 2007
Results First Posted : July 2, 2017
Last Update Posted : July 2, 2017

Sponsor:
M.D. Anderson Cancer Center

Collaborator:
Schering-Plough

Information provided by (Responsible Party):
M.D. Anderson Cancer Center

Study Details | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Study Type	Interventional
Study Design	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Single (Participant); Primary Purpose: Treatment
Condition	**Melanoma**
Interventions	Drug: Temozolomide (TMZ) Drug: Pegylated **Interferon Alpha-2b** (PGI)
Enrollment	55

Participant Flow

Go to

Recruitment Details	Recruitment Period: August 31, 2006 to May 10, 2011. All recruitment done at The University of Texas MD Anderson Cancer Center.
Pre-assignment Details	Three participants of 55 enrolled were excluded due to ineligibility prior to assignment to groups.

Arm/Group Title	Temozolomide (TMZ)	Temozolomide (TMZ) + Pegylated Interferon-alpha 2b (PGI)
Arm/Group Description	TMZ 150 mg/m^2 oral once daily for 7 days, followed by 7 days off (alternating weekly) for a total of 8 weeks.	TMZ 150 mg/m^2 oral once daily for 7 days, followed by 7 days off (alternating weekly) and PGI 0.5 mcg/kg subcutaneous injection once weekly for a total of 8 weeks.
Period Title: **Overall Study**		

Started	27	25
Completed	26	24
Not Completed	1	1
Reason Not Completed		
Disease Progression	1	1

Baseline Characteristics

Go to

Arm/Group Title	TMZ Alone	TMZ + PGI	Total
Arm/Group Description	TMZ 150 mg/m^2 oral once daily for 7 days, followed by 7 days off (alternating weekly) for a total of 8 weeks.	TMZ 150 mg/m^2 oral once daily for 7 days, followed by 7 days off (alternating weekly) and PGI 0.5 mcg/kg subcutaneous injection once weekly for a total of 8 weeks.	Total of all reporting groups
Overall Number of Baseline Participants	27	25	52
Baseline Analysis Population Description	[Not Specified]		
Age, Continuous Median (Full Range) Unit of measure: Years			
Number Analyzed	27 participants	25 participants	52 participants
	58 (31 to 71)	62 (32 to 82)	60 (31 to 82)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants			
Number Analyzed	27 participants	25 participants	52 participants
Female	14 51.9%	9 36.0%	23 44.2%
Male	13 48.1%	16 64.0%	29 55.8%
Region of Enrollment Measure Type: Count of Participants Unit of measure: Participants			
Number Analyzed	27 participants	25 participants	52 participants
United States	27 100.0%	25 100.0%	52 100.0%

Outcome Measures

Go to

1. Primary Outcome

Title	Response to Neoadjuvant Therapy by Therapy Arms: Clinical Response Rates (CR + PR + SD)
▼ Description	Response to neoadjuvant therapy reported as number of participants with clinical response, defined as Complete Response (CR), Partial Response (PR) or Stable Disease (SD). Clinical Complete Response (CR): Disappearance of all clinical evidence of visible tumor. Partial Response (PR) : 30% or > decrease in the sum of the of the longest diameter of target lesions, taking as reference the baseline sum longest diameter persisting for at least 4 weeks. Progressive Disease (PD): > 20% increase in sum of longest diameter of target lesions, reference baseline sum longest diameter. Appearance new lesions and/or unequivocal progression of existing non-target lesions. Stable Disease (SD): Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease, reference smallest sum longest diameter since treatment started.
Time Frame	Evaluated after a total of 8 weeks of therapy before definitive surgery.

▼ Outcome Measure Data

▼ Analysis Population Description
[Not Specified]

Arm/Group Title	TMZ Alone		TMZ + PGI	
▼ Arm/Group Description:	TMZ 150 mg/m^2 oral once daily for 7 days, followed by 7 days off (alternating weekly) for a total of 8 weeks.		TMZ 150 mg/m^2 oral once daily for 7 days, followed by 7 days off (alternating weekly) and PGI 0.5 mcg/kg subcutaneous injection once weekly for a total of 8 weeks.	
Overall Number of Participants Analyzed	18		18	
Measure Type: Count of Participants Unit of Measure: Participants				
CR, PR, SD	4	22.2%	7	38.9%
PD	14	77.8%	11	61.1%

2. Primary Outcome

Title	Response to Neoadjuvant Therapy: Overall Clinical Responses
▼ Description	Response to neoadjuvant therapy reported as number of participants with clinical response, defined as Clinical Complete Response (CR): Disappearance of all clinical evidence of visible tumor. Partial Response (PR) : 30% or > decrease in the sum of the of the longest diameter of target lesions, taking as reference the baseline sum longest diameter persisting for at least 4 weeks. Progressive Disease (PD): > 20% increase in sum of longest diameter of target lesions, reference baseline sum longest diameter. Appearance new lesions and/or unequivocal progression of existing non-target lesions. Stable Disease (SD): Neither sufficient shrinkage to qualify for partial response nor sufficient increase to qualify for progressive disease, reference smallest sum longest diameter since treatment started.
Time Frame	Evaluated after a total of 8 weeks of therapy before definitive surgery.

▼ Outcome Measure Data

▼ Analysis Population Description
[Not Specified]

Arm/Group Title	Overall Study
▼ Arm/Group Description:	Arm A: TMZ 150 mg/m^2 oral once daily for 7 days, followed by 7 days off (alternating weekly) for a total of 8 weeks. Arm B: TMZ 150 mg/m^2 oral once daily for 7 days, followed by 7 days off (alternating weekly) and PGI 0.5 mcg/kg subcutaneous injection once weekly for a total of 8 weeks.

Overall Number of Participants Analyzed	50	
Measure Type: Count of Participants Unit of Measure: Participants		
Complete Response	1	2.0%
Partial Response	15	30.0%
Stable Disease	3	6.0%
Progressive Disease	31	62.0%

Adverse Events

Go to

Time Frame	Adverse event data were collected from first cycle (8 weeks) of neoadjuvant therapy before undergoing surgical resection and up to 3 additional cycles (24 weeks) following definitive surgery as adjuvant therapy for total of 32 weeks.
Adverse Event Reporting Description	[Not Specified]

Arm/Group Title	TMZ Alone	TMZ + PGI
Arm/Group Description	TMZ 150 mg/m^2 oral once daily for 7 days, followed by 7 days off (alternating weekly) for a total of 8 weeks.	TMZ 150 mg/m^2 oral once daily for 7 days, followed by 7 days off (alternating weekly) and PGI 0.5 mcg/kg subcutaneous injection once weekly for a total of 8 weeks.

All-Cause Mortality

	TMZ Alone		TMZ + PGI	
	Affected / at Risk (%)		Affected / at Risk (%)	
Total	--/--		--/--	

Serious Adverse Events

	TMZ Alone		TMZ + PGI	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	0/27 (0.00%)		8/25 (32.00%)	
Blood and lymphatic system disorders				
LEUKOCYTES INCREASED/Leukocytosis † 1	0/27 (0.00%)	0	1/25 (4.00%)	1
Investigations				
NEUTROPHILS INCREASED (ANC/AGC) † 1	0/27 (0.00%)	0	1/25 (4.00%)	1
LYMPHOPENIA † 1	0/27 (0.00%)	0	3/25 (12.00%)	3
PLATELETS DECREASED † 1	0/27 (0.00%)	0	3/25 (12.00%)	3

† Indicates events were collected by systematic assessment

1 Term from vocabulary, CTCAE (4.0)

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	4%			
	TMZ Alone		**TMZ + PGI**	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	26/27 (96.30%)		24/25 (96.00%)	
Blood and lymphatic system disorders				
LEUKOCYTES INCREASED/Leukocytosis † 1	2/27 (7.41%)	2	7/25 (28.00%)	7
Gastrointestinal disorders				
CONSTIPATION † 1	11/27 (40.74%)	11	14/25 (56.00%)	14
DIARRHEA † 1	0/27 (0.00%)	0	5/25 (20.00%)	5
INDIGESTION † 1	1/27 (3.70%)	1	0/25 (0.00%)	0
VOMITING † 1	4/27 (14.81%)	4	6/25 (24.00%)	6
General disorders				
FATIGUE † 1	12/27 (44.44%)	12	17/25 (68.00%)	17
FEVER WITHOUT NEUTROPENIA † 1	0/27 (0.00%)	0	3/25 (12.00%)	3
FLU-LIKE SYNDROME † 1	1/27 (3.70%)	1	7/25 (28.00%)	7
HEARTBURN † 1	0/27 (0.00%)	0	2/25 (8.00%)	2
NAUSEA † 1	11/27 (40.74%)	11	16/25 (64.00%)	16
RIGORS/CHILLS † 1	0/27 (0.00%)	0	1/25 (4.00%)	1
Injury, poisoning and procedural complications				
INJECTION SITE REACTION † 1	1/27 (3.70%)	1	14/25 (56.00%)	14
Investigations				
ALANINE TRANSAMINASE (ALT) INCREASED † 1	0/27 (0.00%)	0	6/25 (24.00%)	6
ASPARTATE AMINOTRANSFERASE (AST) INCREASED † 1	0/27 (0.00%)	0	6/25 (24.00%)	6
ELEVEVATED Serum Glutamic-Oxaloacetic Transaminase (SGOT) † 1	0/27 (0.00%)	0	1/25 (4.00%)	1
HEMOGLOBIN INCREASED † 1	3/27 (11.11%)	3	4/25 (16.00%)	4
LEUKOPENIA † 1	2/27 (7.41%)	2	5/25 (20.00%)	5
LYMPHOCYTE COUNT DECREASED † 1	0/27 (0.00%)	0	1/25 (4.00%)	1
LYMPHOPENIA † 1	5/27 (18.52%)	5	7/25 (28.00%)	7
NEUTROPHILS DECREASED (Absolute neutrophil count/ANC) † 1	2/27 (7.41%)	2	7/25 (28.00%)	7
PLATELETS DECREASED † 1	5/27 (18.52%)	5	10/25 (40.00%)	10
WHITE BLOOD CELL DECREASED † 1	0/27 (0.00%)	0	1/25 (4.00%)	1
Metabolism and nutrition disorders				
ANOREXIA † 1	10/27 (37.04%)	10	9/25 (36.00%)	9
HYPERGLYCEMIA † 1	0/27 (0.00%)	0	2/25 (8.00%)	2
HYPOCALCEMIA † 1	0/27 (0.00%)	0	1/25 (4.00%)	1
HYPOMAGNESEMIA † 1	0/27 (0.00%)	0	1/25 (4.00%)	1
Musculoskeletal and connective tissue disorders				
PAIN (EXTREMITY-LIMBS) † 1	2/27 (7.41%)	2	1/25 (4.00%)	1
PAIN (MUSCLE) † 1	0/27 (0.00%)	0	1/25 (4.00%)	1
Nervous system disorders				
DIZZINESS † 1	1/27 (3.70%)	1	0/25 (0.00%)	0

PAIN (HEAD/HEADACHE) † 1	8/27 (29.63%)	8	16/25 (64.00%)	16
TASTE ALTERATION † 1	1/27 (3.70%)	1	3/25 (12.00%)	3
Psychiatric disorders				
MOOD ALTERATION † 1	0/27 (0.00%)	0	3/25 (12.00%)	3
Renal and urinary disorders				
CYSTITIS † 1	0/27 (0.00%)	0	1/25 (4.00%)	1
Skin and subcutaneous tissue disorders				
ALOPECIA † 1	1/27 (3.70%)	1	2/25 (8.00%)	2
PAIN (SKIN) † 1	0/27 (0.00%)	0	1/25 (4.00%)	1
PRURITUS † 1	1/27 (3.70%)	1	3/25 (12.00%)	3
PRURITUS/ITCHING † 1	1/27 (3.70%)	1	4/25 (16.00%)	4
RASH/DESQUAMATION † 1	0/27 (0.00%)	0	3/25 (12.00%)	3
SWEATING † 1	0/27 (0.00%)	0	1/25 (4.00%)	1

† Indicates events were collected by systematic assessment

1 Term from vocabulary, CTCAE (4.0)

Limitations and Caveats

Go to

[Not Specified]

More Information

Go to

Certain Agreements

All Principal Investigators ARE employed by the organization sponsoring the study.

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