Trial record **1 of 1** for: CERP | pain

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RCT Comparing the Analgesic Efficacy of 4 Therapeutic Strategies Based on 4 Different Major Opioids (Fentanyl, Oxycodone, Buprenorphine vs Morphine) in Cancer Patients With Moderate/Severe Pain, at the Moment of Starting 3rd Step of WHO Analgesic Ladder. (CERP)

ClinicalTrials.gov Identifier: NCT01809106

Recruitment Status : Completed
First Posted : March 12, 2013
Results First Posted : November 20, 2015
Last Update Posted : December 24, 2015

Sponsor:
Mario Negri Institute for Pharmacological Research

Information provided by (Responsible Party):
Mario Negri Institute for Pharmacological Research

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: None (Open Label); Primary Purpose: Treatment
Conditions	Cancer Cancer **Pain**
Interventions	Drug: Morphine Drug: Fentanyl Drug: Buprenorphine Drug: Oxycodone
Enrollment	518

Participant Flow

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Recruitment Details	Date of First Enrollment: May 2014 Date of last enrollment: July 2014
Pre-assignment Details	

Arm/Group Title	Morphine	Oxycodone	Buprenorphine	Fentanyl
Arm/Group Description	Morphine: 60 mg /24 ore	Oxycodone: 40 mg /24 ore	Buprenorphine: 35 microg/h	Fentanyl: 25 microg/h
Period Title: **Overall Study**				
Started	130	130	130	128
Completed	122	125	127	124
Not Completed	8	5	3	4

Baseline Characteristics

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Arm/Group Title		Morphine	Oxycodone	Buprenorphine	Fentanyl	Total
▼ Arm/Group Description		Morphine: 60 mg /24 ore	Oxycodone: 40 mg /24 ore	Buprenorphine: 35 microg/h	Fentanyl: 25 microg/h	Total of all reporting groups
Overall Number of Baseline Participants		122	125	127	124	498
▼ Baseline Analysis Population Description		[Not Specified]				
Age, Continuous Mean (Standard Deviation) Unit of measure: Years						
	Number Analyzed	122 participants	125 participants	127 participants	124 participants	498 participants
		67.5 (11.7)	66.9 (11.1)	65.2 (13.5)	68 (10.6)	66.9 (11.8)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants						
	Number Analyzed	122 participants	125 participants	127 participants	124 participants	498 participants
	Female	55 45.1%	53 42.4%	59 46.5%	54 43.5%	221 44.4%
	Male	67 54.9%	72 57.6%	68 53.5%	70 56.5%	277 55.6%

Outcome Measures

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1. Primary Outcome

Title	Proportion of Non-Responder (NR) Participants
Description	Evaluation of the proportion of Non-Responder (NR) participants. NR correspond to the subjects who do not report any analgesic effects, with a P.I.D. (pain intensity difference) from visit 6 and visit 1 =/< 0%, (using a 0-10 NRS). It includes the situations of average pain intensity “stable” or “worsened” at day 28 compared with baseline values.
Time Frame	28 days

Outcome Measure Data

Analysis Population Description
Intention-to-treat

Arm/Group Title	Morphine	Oxycodone	Buprenorphine	Fentanyl
Arm/Group Description:	Morphine: 60 mg /24 ore	Oxycodone: 40 mg /24 ore	Buprenorphine: 35 microg/h	Fentanyl: 25 microg/h
Overall Number of Participants Analyzed	122	125	127	124
Measure Type: Number Unit of Measure: participants				
	14	18	14	11

2. Secondary Outcome

Title	Proportion of Full-responder
Description	Evaluation of the proportion of subjects who report full analgesia (full responders: FR). FR is operationally defined as a patient with a P.I.D. =/> 30% from visit 6 and visit 1 (NRS 0 to 10).
Time Frame	28 days

Outcome Measure Data

Analysis Population Description
[Not Specified]

Arm/Group Title	Morphine	Oxycodone	Buprenorphine	Fentanyl
Arm/Group Description:	Morphine: 60 mg /24 ore	Oxycodone: 40 mg /24 ore	Buprenorphine: 35 microg/h	Fentanyl: 25 microg/h
Overall Number of Participants Analyzed	122	125	127	124
Measure Type: Number Unit of Measure: participants				
	89	90	95	88

3. Other Pre-specified Outcome

Title	The Opioid Escalation Index
▼ Description	The proportion of subjects with an increase of opioid daily dose > 5% compared with the basal dosage (OEI%).
Time Frame	28 days

▼ Outcome Measure Data

▼ Analysis Population Description
[Not Specified]

Arm/Group Title	Morphine	Oxycodone	Buprenorphine	Fentanyl
▼ Arm/Group Description:	Morphine: 60 mg /24 ore	Oxycodone: 40 mg /24 ore	Buprenorphine: 35 microg/h	Fentanyl: 25 microg/h
Overall Number of Participants Analyzed	122	125	127	124
Measure Type: Number Unit of Measure: participants				
	13	24	18	45

Adverse Events

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Time Frame	[Not Specified]
Adverse Event Reporting Description	[Not Specified]

Arm/Group Title	Morphine	Oxycodone	Buprenorphine	Fentanyl
▼ Arm/Group Description	Morphine: 60 mg /24 ore	Oxycodone: 40 mg /24 ore	Buprenorphine: 35 microg/h	Fentanyl: 25 microg/h

All-Cause Mortality

	Morphine		Oxycodone		Buprenorphine		Fentanyl	
	Affected / at Risk (%)		Affected / at Risk (%)		Affected / at Risk (%)		Affected / at Risk (%)	
Total	--/--		--/--		--/--		--/--	

▼ **Serious Adverse Events**

	Morphine		Oxycodone		Buprenorphine		Fentanyl	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	5/122 (4.10%)		1/125 (0.80%)		1/127 (0.79%)		5/124 (4.03%)	
Gastrointestinal disorders								
bowel occlusion	1/122 (0.82%)	1	0/125 (0.00%)	0	0/127 (0.00%)	0	1/124 (0.81%)	1
asthenia	0/122 (0.00%)	0	0/125 (0.00%)	0	0/127 (0.00%)	0	1/124 (0.81%)	1
oral cavity bleeding	0/122 (0.00%)	0	0/125 (0.00%)	0	1/127 (0.79%)	2	0/124 (0.00%)	0
General disorders								
exitus	0/122 (0.00%)	0	0/125 (0.00%)	0	0/127 (0.00%)	0	1/124 (0.81%)	1

decline general condition	0/122 (0.00%)	0	1/125 (0.80%)	1	0/127 (0.00%)	0	1/124 (0.81%)	1
hyperpyrexia	2/122 (1.64%)	2	0/125 (0.00%)	0	0/127 (0.00%)	0	0/124 (0.00%)	0
Hepatobiliary disorders								
hepatic disorder	0/122 (0.00%)	0	0/125 (0.00%)	0	0/127 (0.00%)	0	1/124 (0.81%)	1
Nervous system disorders								
hyperalgesia	1/122 (0.82%)	1	0/125 (0.00%)	0	0/127 (0.00%)	0	0/124 (0.00%)	0
Respiratory, thoracic and mediastinal disorders								
dyspnea	1/122 (0.82%)	1	0/125 (0.00%)	0	0/127 (0.00%)	0	1/124 (0.81%)	1
atelectasis	1/122 (0.82%)	1	0/125 (0.00%)	0	0/127 (0.00%)	0	0/124 (0.00%)	0

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	0%

	Morphine		Oxycodone		Buprenorphine		Fentanyl	
	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events	Affected / at Risk (%)	# Events
Total	103/122 (84.43%)		98/125 (78.40%)		108/127 (85.04%)		95/124 (76.61%)	
General disorders								
drowsiness	79/122 (64.75%)	79	74/125 (59.20%)	74	81/127 (63.78%)	81	70/124 (56.45%)	70
Confusion	59/122 (48.36%)	59	55/125 (44.00%)	55	61/127 (48.03%)	61	46/124 (37.10%)	46

Limitations and Caveats

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[Not Specified]

More Information

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Certain Agreements

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

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

Results Point of Contact

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Publications:

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Apolone G, Corli O, Caraceni A, Negri E, Deandrea S, Montanari M, Greco MT; Cancer Pain Outcome Research Study Group (CPOR SG)

Investigators. Pattern and quality of care of cancer pain management. Results from the Cancer Pain Outcome Research Study Group. Br J Cancer. 2009 May 19;100(10):1566-74. doi: 10.1038/sj.bjc.6605053. Epub 2009 Apr 28.

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Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

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