Trial record **1 of 1** for: CR012601
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Placebo-controlled Trial With OROS Hydromorphone Hydrochloride to Treat Patients With Moderate to Severe Pain Induced by Osteoarthritis of the Hip or the Knee

This study has been completed.

Sponsor:
Janssen-Cilag International NV

Information provided by (Responsible Party):
Janssen-Cilag International NV

ClinicalTrials.gov Identifier:
NCT00980798

First received: September 18, 2009
Last updated: April 8, 2014
Last verified: April 2014
History of Changes

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Results First Received: August 12, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Pain Osteoarthritis, Hip Osteoarthritis, Knee
Interventions:	Drug: OROS hydromorphone HCl Drug: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
The first subject attended the first study visit on 05 October 2007, and the last subject completed the last study visit on 24 November 2008.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Placebo	Placebo daily for 16 weeks
OROS Hydromorphone HCl	4 to 32 mg taken orally once daily for 16 weeks

Participant Flow: Overall Study

	Placebo	**OROS Hydromorphone HCl**

STARTED	**149**	**139**
COMPLETED	**116**	**84**
NOT COMPLETED	**33**	**55**
Adverse Event	**7**	**36**
Lack of Efficacy	**16**	**5**
Lost to Follow-up	**0**	**1**
Physician Decision	**2**	**1**
Withdrawal by Subject	**8**	**11**
Other	**0**	**1**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Placebo	Placebo daily for 16 weeks
OROS Hydromorphone HCl	4 to 32 mg taken orally once daily for 16 weeks
Total	Total of all reporting groups

Baseline Measures

	Placebo	**OROS Hydromorphone HCl**	**Total**
Number of Participants [units: participants]	**149**	**139**	**288**
Age [units: years] Mean (Standard Deviation)	**64.9 (10.37)**	**65.1 (9.96)**	**65 (10.16)**
Gender [units: participants]			
Female	**101**	**107**	**208**
Male	**48**	**32**	**80**

Outcome Measures

Hide All Outcome Measures

1. Primary: Analgesic Effect as Assessed by Brief Pain Inventory (BPI) Item 5 Score (Pain on Average) [Time Frame: At each study visit from screening to week 16]

Measure Type	Primary
Measure Title	Analgesic Effect as Assessed by Brief Pain Inventory (BPI) Item 5 Score (Pain on Average)
Measure Description	The analgesic effect was assessed by the BPI item 5 “pain on average” using a 0 to 10 numeric rating scale, with 0

	being "no pain" and 10 being "pain as bad as you can imagine".
Time Frame	At each study visit from screening to week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The primary population for the efficacy analyses was the intention to treat (ITT) population: all randomised patients who received at least one dose of study drug excluding patients who had no post-baseline efficacy data. This population included patients who discontinued early owing to lack of efficacy or other reasons.

Reporting Groups

	Description
Placebo	Placebo daily for 16 weeks
OROS Hydromorphone HCl	4 to 32 mg taken orally once daily for 16 weeks

Measured Values

	Placebo	**OROS Hydromorphone HCl**
Number of Participants Analyzed [units: participants]	**143**	**132**
Analgesic Effect as Assessed by Brief Pain Inventory (BPI) Item 5 Score (Pain on Average) [units: units on a scale] Mean (Standard Deviation)		
Screening	**6.4 (0.94)**	**6.4 (1.05)**
Baseline (Visit 1)	**6.5 (0.94)**	**6.6 (1.04)**
Visit 2	**5.2 (1.43)**	**5.0 (1.63)**
Visit 3	**4.8 (1.66)**	**4.6 (1.66)**
Visit 4	**4.3 (1.72)**	**4.0 (1.85)**
Visit 5	**3.9 (1.9)**	**3.9 (2.02)**
Visit 6	**3.7 (1.97)**	**3.5 (1.88)**
Visit 7	**3.6 (1.99)**	**3.4 (1.96)**
Visit 8	**4.0 (2.3)**	**4.1 (2.2)**
Visit 9	**4.2 (2.27)**	**4.4 (2.23)**

Statistical Analysis 1 for Analgesic Effect as Assessed by Brief Pain Inventory (BPI) Item 5 Score (Pain on Average)

Groups [1]	All groups
Method [2]	Mixed-model regression analysis
P Value [3]	0.1212
Mean Difference (Net) [4]	-0.2365
95% Confidence Interval	-0.5357 to 0.0627

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The F test for treatment tested the null hypothesis of no treatment difference. Assuming that 3 baseline measures and 7 post baseline measures were collected 81 patients were required per group to detect a difference of 1 point in the BPI measure with 90% power at a significance level of 5%. To allow for a drop-out rate of approximately 40%, the study planned to recruit 135 patients per group (i.e. 270 in total).

[2]	Other relevant method information, such as adjustments or degrees of freedom:
	The difference above is presented as the difference OROS hydromorphone HCl minus placebo, so negative scores favour OROS hydromorphone HCl.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No adjustment for multiple comparisons necessary, as only 1 primary hypothesis was tested. Threshold for statistical significance was 0.05.
[4]	Other relevant estimation information:
	The analysis was adjusted for baseline BPI item 5 score, time on study, and whether the primary affected joint was the hip or knee.

2. Secondary: The Number of Patients Discontinuing From the Trial Due to the Occurrence of an Adverse Event [Time Frame: At each study visit from baseline until week 16]

Measure Type	Secondary
Measure Title	The Number of Patients Discontinuing From the Trial Due to the Occurrence of an Adverse Event
Measure Description	The number of patients dropping out of the study owing to adverse events will be presented for each treatment group.
Time Frame	At each study visit from baseline until week 16
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Safety population: All randomised patients who received at least one dose of study drug.

Reporting Groups

	Description
Placebo	Placebo daily for 16 weeks
OROS Hydromorphone HCl	4 to 32 mg taken orally once daily for 16 weeks

Measured Values

	Placebo	OROS Hydromorphone HCl
Number of Participants Analyzed [units: participants]	**149**	**139**
The Number of Patients Discontinuing From the Trial Due to the Occurrence of an Adverse Event [units: participants]	**7**	**36**

No statistical analysis provided for The Number of Patients Discontinuing From the Trial Due to the Occurrence of an Adverse Event

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse were collected from signing of informed consent until the end of the study (week 16 or later after complete tapering off of study medication)
Additional Description	No text entered.

Reporting Groups

	Description
Placebo	Placebo daily for 16 weeks
OROS Hydromorphone HCl	4 to 32 mg taken orally once daily for 16 weeks

Serious Adverse Events

	Placebo	OROS Hydromorphone HCl
Total, serious adverse events		
# participants affected / at risk	**7/149 (4.70%)**	**4/139 (2.88%)**
Cardiac disorders		
Atrial fibrillation * 1		
# participants affected / at risk	**1/149 (0.67%)**	**0/139 (0.00%)**
Myocardial infarction * 1		
# participants affected / at risk	**1/149 (0.67%)**	**0/139 (0.00%)**
Supraventricular tachycardia * 1		
# participants affected / at risk	**1/149 (0.67%)**	**0/139 (0.00%)**
Gastrointestinal disorders		
Dyspepsia * 1		
# participants affected / at risk	**0/149 (0.00%)**	**2/139 (1.44%)**
Abdominal pain upper * 1		
# participants affected / at risk	**0/149 (0.00%)**	**1/139 (0.72%)**
Diarrhoea * 1		
# participants affected / at risk	**0/149 (0.00%)**	**1/139 (0.72%)**
Nausea * 1		
# participants affected / at risk	**0/149 (0.00%)**	**1/139 (0.72%)**
General disorders		
Asthenia * 1		
# participants affected / at risk	**0/149 (0.00%)**	**1/139 (0.72%)**
Infections and infestations		
Pyelonephritis acute * 1		
# participants affected / at risk	**1/149 (0.67%)**	**0/139 (0.00%)**
Injury, poisoning and procedural complications		
Skin laceration * 1		
# participants affected / at risk	**0/149 (0.00%)**	**1/139 (0.72%)**
Road traffic accident * 1		
# participants affected / at risk	**1/149 (0.67%)**	**0/139 (0.00%)**
Metabolism and nutrition disorders		
Hyperglycaemia * 1		
# participants affected / at risk	**1/149 (0.67%)**	**0/139 (0.00%)**
Nervous system disorders		
Cerebrovascular accident * 1		
# participants affected / at risk	**1/149 (0.67%)**	**1/139 (0.72%)**
Skin and subcutaneous tissue disorders		

Dermatitis allergic * 1		
# participants affected / at risk	1/149 (0.67%)	0/139 (0.00%)
Surgical and medical procedures		
Cardioversion * 1		
# participants affected / at risk	1/149 (0.67%)	0/139 (0.00%)
Vascular disorders		
Hypertensive crisis * 1		
# participants affected / at risk	0/149 (0.00%)	1/139 (0.72%)

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 11.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse were collected from signing of informed consent until the end of the study (week 16 or later after complete tapering off of study medication)
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Placebo	Placebo daily for 16 weeks
OROS Hydromorphone HCl	4 to 32 mg taken orally once daily for 16 weeks

Other Adverse Events

	Placebo	OROS Hydromorphone HCl
Total, other (not including serious) adverse events		
# participants affected / at risk	50/149 (33.56%)	106/139 (76.26%)
Ear and labyrinth disorders		
Vertigo * 1		
# participants affected / at risk	4/149 (2.68%)	10/139 (7.19%)
Gastrointestinal disorders		
Constipation * 1		
# participants affected / at risk	10/149 (6.71%)	63/139 (45.32%)
Nausea * 1		
# participants affected / at risk	10/149 (6.71%)	41/139 (29.50%)
Vomiting * 1		
# participants affected / at risk	2/149 (1.34%)	15/139 (10.79%)
Dry mouth * 1		
# participants affected / at risk	7/149 (4.70%)	11/139 (7.91%)
Metabolism and nutrition disorders		

Anorexia * 1		
# participants affected / at risk	**1/149 (0.67%)**	**8/139 (5.76%)**
Nervous system disorders		
Somnolence * 1		
# participants affected / at risk	**22/149 (14.77%)**	**45/139 (32.37%)**
Dizziness * 1		
# participants affected / at risk	**5/149 (3.36%)**	**15/139 (10.79%)**
Headache * 1		
# participants affected / at risk	**4/149 (2.68%)**	**8/139 (5.76%)**
Skin and subcutaneous tissue disorders		
Pruritus * 1		
# participants affected / at risk	**1/149 (0.67%)**	**10/139 (7.19%)**
Hyperhidrosis * 1		
# participants affected / at risk	**0/149 (0.00%)**	**7/139 (5.04%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 11.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
Concomitant and rescue medication were permitted in the study. This may be why the results in the placebo arm so closely resemble those in the treatment arm. Patients were also less severely impacted by the underlying disease than in other studies.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** 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.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☑ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Title: EMEA Medical Affairs Director Analgesia
Organization: Janssen-Cilag Ireland
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No publications provided

Responsible Party:	Janssen-Cilag International NV
ClinicalTrials.gov Identifier:	NCT00980798 History of Changes
Other Study ID Numbers:	**CR012601**, HOP Trial
Study First Received:	September 18, 2009
Results First Received:	August 12, 2010
Last Updated:	April 8, 2014
Health Authority:	Belgium: Ministry of Social Affairs, Public Health and the Environment

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