Trial record **1 of 1** for: FEN-PAI 3002
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A Study to Evaluate the Safety and Tolerability of Fentanyl Iontophoretic Transdermal System (Fentanyl-ITS) in the Management of Post-Surgery Pain

This study has been terminated.

(The study was prematurely discontinued since study medication was no longer available.)

Sponsor:
Janssen-Cilag G.m.b.H

Information provided by (Responsible Party):
Janssen-Cilag G.m.b.H

ClinicalTrials.gov Identifier:
NCT01804673

First received: March 4, 2013
Last updated: August 2, 2013
Last verified: August 2013
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: May 1, 2013

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Postoperative Pain
Intervention:	Drug: Fentanyl-ITS

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
No text entered.

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
Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Participant Flow: Overall Study

	Fentanyl
STARTED	**174**

Completed Hour 24	**170**
Completed Hour 48	**79**
Completed Hour 72	**36**
COMPLETED	**34**
NOT COMPLETED	**140**
Adverse Event	**4**
Withdrawal by Subject	**1**
Lack of Efficacy	**9**
Change to Oral Therapy	**37**
No Further Therapy Required	**84**
Use of Prohibited Medication	**1**
Unspecified	**4**

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
Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Baseline Measures

	Fentanyl
Overall Participants [units: participants]	**174**
Age [units: Years] Mean (Standard Deviation)	**49.3 (16.7)**
Gender [units: Participants]	
Female	**86**
Male	**88**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants With Global Assessment of Pain at Hour 24 [Time Frame: Hour 24]

Measure Type	Primary
Measure Title	Percentage of Participants With Global Assessment of Pain at Hour 24
Measure Description	Participants were asked to rate their overall global assessment of pain therapy with study treatment on a 4-point verbal rating scale (poor, fair, good, excellent). Outcome of 'good' or 'excellent ' was recorded as Response while

	outcome of 'poor' or 'fair' was recorded as No response.
Time Frame	Hour 24
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.
Efficacy analysis set included all participants who received the study treatment at least once and who had efficacy data for the primary parameter after the 0 hour Baseline visit.

Reporting Groups

	Description
Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Measured Values

	Fentanyl
Overall Participants [units: participants]	**170**
Percentage of Participants With Global Assessment of Pain at Hour 24 [units: percent of participants] Number (95% Confidence Interval)	
Response	**82.9** **(76.4 to 88.3)**
No response	**17.1** **(11.7 to 23.6)**

No statistical analysis provided for Percentage of Participants With Global Assessment of Pain at Hour 24

2. Secondary: Number of Hours Per Day With Average Pain Intensity Less Than or Equal to 4 [Time Frame: Baseline to Hour 24, Hour 24 to Hour 48 and Hour 48 to Hour 72]

Measure Type	Secondary
Measure Title	Number of Hours Per Day With Average Pain Intensity Less Than or Equal to 4
Measure Description	Number of hours per day with average pain intensity less than or equal to 4 was measured on a 11-point Numeric Rating Scale (NRS) (range 0 to 10, 0=no pain; 4=mild pain; 10=strongest pain imaginable). If the participant was sleeping at time of measurement, pain intensity was assumed to be less than or equal to 4.
Time Frame	Baseline to Hour 24, Hour 24 to Hour 48 and Hour 48 to Hour 72
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.
Efficacy analysis set included all participants who received the study treatment at least once and who had efficacy data for the primary parameter after 0 hour Baseline visit. 'N' (number of participants analyzed) signifies participants evaluable for this measure and ‘n’ signifies participants evaluable for this measure at specified time point.

Reporting Groups

	Description

Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Measured Values

	Fentanyl
Overall Participants [units: participants]	**125**
Number of Hours Per Day With Average Pain Intensity Less Than or Equal to 4 [units: hours] Mean (Standard Deviation)	
Baseline to Hour 24 (n=125)	**21.3 (4.3)**
Hour 24 to Hour 48 (n= 57)	**22.2 (4.1)**
Hour 48 to Hour 72 (n= 23)	**22.7 (2.4)**

No statistical analysis provided for Number of Hours Per Day With Average Pain Intensity Less Than or Equal to 4

3. Secondary: Change From Baseline in Pain Intensity Rating at Hour 24, 48 and 72 [Time Frame: Baseline, Hour 24, 48 and 72]

Measure Type	Secondary
Measure Title	Change From Baseline in Pain Intensity Rating at Hour 24, 48 and 72
Measure Description	Nursing staff asked the participants to rate their current pain intensity on 11-point NRS (range 0 to 10, 0= no pain; 10= strongest pain imaginable).
Time Frame	Baseline, Hour 24, 48 and 72
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.
Efficacy analysis set included all participants who received the study treatment at least once and who had efficacy data for primary parameter after 0 hour Baseline visit. 'N' (number of participants analyzed) signifies participants evaluable for this measure and 'n' signifies participants evaluable for this measure at specified time point.

Reporting Groups

	Description
Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Measured Values

	Fentanyl
Overall Participants [units: participants]	**168**
Change From Baseline in Pain Intensity Rating at Hour 24, 48 and 72 [units: units on scale] Mean (Standard Deviation)	
Baseline (n= 168)	**3.0 (1.2)**
Change at Hour 24 (n= 157)	**-0.9 (1.7)**
Change at Hour 48 (n= 73)	**-1.2 (1.8)**
Change at Hour 72 (n= 31)	**-1.3 (2.1)**

No statistical analysis provided for Change From Baseline in Pain Intensity Rating at Hour 24, 48 and 72

4. Secondary: Time Spent Out of the Bed Per Day by the Participant [Time Frame: Baseline to Hour 24, Hour 24 to Hour 48 and Hour 48 to Hour 72]

Measure Type	Secondary
Measure Title	Time Spent Out of the Bed Per Day by the Participant
Measure Description	Participants were asked to enter the time in hours spend out of bed during the last 24 hours in the participant diary.
Time Frame	Baseline to Hour 24, Hour 24 to Hour 48 and Hour 48 to Hour 72
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.
Efficacy analysis set included all participants who received the study treatment at least once and who had efficacy data for primary parameter after 0 hour Baseline visit. 'N' (number of participants analyzed) signifies participants evaluable for this measure and 'n' signifies participants evaluable for this measure at specified time point.

Reporting Groups

	Description
Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Measured Values

	Fentanyl
Overall Participants [units: participants]	**126**
Time Spent Out of the Bed Per Day by the Participant [units: minutes] Mean (Standard Deviation)	
Baseline to Hour 24 (n= 126)	**38.1 (94.5)**
Hour 24 to Hour 48 (n= 50)	**87.5 (121.6)**
Hour 48 to Hour 72 (n= 26)	**146.7 (193.9)**

No statistical analysis provided for Time Spent Out of the Bed Per Day by the Participant

5. Secondary: Time to Mobilization [Time Frame: Baseline, Hours 24, 48 and 72]

Measure Type	Secondary
Measure Title	Time to Mobilization
Measure Description	Participants were asked to describe their time schedule for particular steps of mobilization by answering specific questions in the participant diary.
Time Frame	Baseline, Hours 24, 48 and 72
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.
Data was not statistically summarized but reported in individual participant listing. Due to excessive missing data it was not possible to calculate valid results for the different stages of mobilization.

Reporting Groups

	Description
Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Measured Values

	Fentanyl
Overall Participants [units: participants]	**0**
Time to Mobilization	

No statistical analysis provided for Time to Mobilization

6. Secondary: Percentage of Participants With Global Assessment of Pain at Hour 48 and 72 [Time Frame: Hours 48 and 72]

Measure Type	Secondary
Measure Title	Percentage of Participants With Global Assessment of Pain at Hour 48 and 72
Measure Description	Participants were asked to give their overall global assessment of pain therapy with study treatment using a 4-point verbal rating scale (poor, fair, good, excellent). Outcome of 'good' or 'excellent ' was recorded as Response while outcome of 'poor' or 'fair' was recorded as No response.
Time Frame	Hours 48 and 72
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.
Efficacy analysis set included all participants who received the study treatment at least once and who had efficacy data for primary parameter after 0 hour Baseline visit. 'N' (number of participants analyzed) signifies participants evaluable for this measure and ‘n’ signifies participants evaluable for this measure at specified time point.

Reporting Groups

	Description
Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Measured Values

	Fentanyl
Overall Participants [units: participants]	**79**
Percentage of Participants With Global Assessment of Pain at Hour 48 and 72 [units: percent of participants] Number (95% Confidence Interval)	
	86.1

Hour 48; Response (n= 79)	**(76.5 to 92.8)**
Hour 48; No response (n= 79)	**12.7 (6.2 to 22.0)**
Hour 48; Missing (n= 79)	**1.3** [1]
Hour 72; Response (n= 36)	**97.2 (85.5 to 99.9)**
Hour 72; No response (n= 36)	**2.8 (0.1 to 14.5)**

[1] Confidence Interval was not calculated for missing participants.

No statistical analysis provided for Percentage of Participants With Global Assessment of Pain at Hour 48 and 72

7. Secondary: Percentage of Participants With Physician Global Assessment of Pain [Time Frame: Hours 24, 48 and 72]

Measure Type	Secondary
Measure Title	Percentage of Participants With Physician Global Assessment of Pain
Measure Description	Physicians were asked to give their overall global assessment of pain therapy with study treatment using a 4-point verbal rating scale (poor, fair, good, excellent). Outcome of 'good' or 'excellent ' was recorded as Response while outcome of 'poor' or 'fair' was recorded as No response.
Time Frame	Hours 24, 48 and 72
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.
Efficacy analysis set included all participants who received the study treatment at least once and who had efficacy data for primary parameter after 0 hour Baseline visit. 'n' signifies those participants evaluable for this measure at the specified time point.

Reporting Groups

	Description
Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Measured Values

	Fentanyl
Overall Participants [units: participants]	**170**
Percentage of Participants With Physician Global Assessment of Pain [units: percent of participants] Number (95% Confidence Interval)	
Hour 24; Response (n= 170)	**88.2 (82.4 to 92.7)**
Hour 24; No response (n= 170)	**11.2 (6.9 to 16.9)**
Hour 24; Missing (n= 170)	**0.6** [1]
Hour 48; Response (n= 79)	**88.6 (79.5 to 94.7)**
Hour 48; No response (n= 79)	**11.4 (5.3 to 20.5)**
	97.2

Hour 72; Response (n= 36)	**(85.5 to 99.9)**
Hour 72; No response (n= 36)	**2.8 (0.1 to 14.5)**

[1] Confidence Interval was not calculated for missing participants.

No statistical analysis provided for Percentage of Participants With Physician Global Assessment of Pain

8. Secondary: Percentage of Participants With Nursing Staff Global Assessment of Pain [Time Frame: Hours 24, 48 and 72]

Measure Type	Secondary
Measure Title	Percentage of Participants With Nursing Staff Global Assessment of Pain
Measure Description	Nursing Staff were asked to give their overall global assessment of pain therapy with study treatment using a 4-point verbal rating scale (poor, fair, good, excellent). Outcome of 'good' or 'excellent ' was recorded as Response while outcome of 'poor' or 'fair' was recorded as No response.
Time Frame	Hours 24, 48 and 72
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.
Efficacy analysis set included all participants who received the study treatment at least once and who had efficacy data for primary parameter after 0 hour Baseline visit. ‘n’ signifies those participants evaluable for this measure at the specified time point.

Reporting Groups

	Description
Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Measured Values

	Fentanyl
Overall Participants [units: participants]	**170**
Percentage of Participants With Nursing Staff Global Assessment of Pain [units: percent of participants] Number (95% Confidence Interval)	
Hour 24; Response (n= 170)	**87.1 (81.1 to 91.7)**
Hour 24; No response (n= 170)	**12.4 (7.8 to 18.3)**
Hour 24; Missing (n= 170)	**0.6** [1]
Hour 48; Response (n= 79)	**88.6 (79.5 to 94.7)**
Hour 48; No response (n= 79)	**11.4 (5.3 to 20.5)**
Hour 72; Response (n= 36)	**97.2 (85.5 to 99.9)**
Hour 72; Missing (n= 36)	**2.8** [1]

[1] Confidence Interval was not calculated for missing participants.

No statistical analysis provided for Percentage of Participants With Nursing Staff Global Assessment of Pain

9. Secondary: Physician's Evaluation of Participant's Ability to Undergo Physiotherapy or Mobilization [Time Frame: Hours 24, 48 and 72]

Measure Type	Secondary
Measure Title	Physician's Evaluation of Participant's Ability to Undergo Physiotherapy or Mobilization
Measure Description	Physicians were asked to rate the participant's ability to undergo physiotherapy or mobilization by responding to following questions of a questionnaire: Part 1 A- Does the surgical procedure performed allow the mobilization of the participant, C- Was the mobilization of the participant limited due to pain, D- Is the participant in a condition to undergo physiotherapy; Part 2 A- Was it possible to mobilize the participant sooner than with other pain therapies, B- Does the participant move more, C- Is the participant less afraid of moving. For Part 1-Question C, 'Partial' indicates that mobilization of participant was moderately limited due to pain.
Time Frame	Hours 24, 48 and 72
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.
Efficacy analysis set included all participants who received the study treatmentat least once and who had efficacy data for primary parameter after 0 hour Baseline visit. 'n' signifies participants evaluable at specified time point for specified item.

Reporting Groups

	Description
Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Measured Values

	Fentanyl
Overall Participants [units: participants]	**170**
Physician's Evaluation of Participant's Ability to Undergo Physiotherapy or Mobilization [units: percent of participants]	
Hour 24 Part 1-Question A; Yes (n=170)	**95.3**
Hour 24 Part 1-Question A; No (n=170)	**4.7**
Hour 24 Part 1-Question C; Yes (n=170)	**16.5**
Hour 24 Part 1-Question C; No (n=170)	**39.4**
Hour 24 Part 1-Question C; Partial (n=170)	**43.5**
Hour 24 Part 1-Question C; Missing (n=170)	**0.6**
Hour 24 Part 1-Question D; Yes (n=170)	**91.8**
Hour 24 Part 1-Question D; No (n=170)	**8.2**
Hour 24 Part 2-Question A; Yes (n=170)	**30.6**
Hour 24 Part 2-Question A; No (n=170)	**62.4**
Hour 24 Part 2-Question A; Missing (n=170)	**7.1**
Hour 24 Part 2-Question B; Yes (n=170)	**54.1**
Hour 24 Part 2-Question B; No (n=170)	**44.7**
Hour 24 Part 2-Question B; Missing (n=170)	**1.2**
Hour 24 Part 2-Question C; Yes (n=170)	**58.8**
Hour 24 Part 2-Question C; No (n=170)	**41.2**
Hour 48 Part 1-Question A; Yes (n=79)	**92.4**
Hour 48 Part 1-Question A; No (n=79)	**2.5**

Hour 48 Part 1-Question A; Missing (n=79)	**5.1**
Hour 48 Part 1-Question C; Yes (n=79)	**8.9**
Hour 48 Part 1-Question C; No (n=79)	**51.9**
Hour 48 Part 1-Question C; Partial (n=79)	**32.9**
Hour 48 Part 1-Question C; Missing (n=79)	**6.3**
Hour 48 Part 1-Question D; Yes (n=79)	**88.6**
Hour 48 Part 1-Question D; No (n=79)	**6.3**
Hour 48 Part 1-Question D; Missing (n=79)	**5.1**
Hour 48 Part 2-Question A; Yes (n=79)	**40.5**
Hour 48 Part 2-Question A; No (n=79)	**53.2**
Hour 48 Part 2-Question A; Missing (n=79)	**6.3**
Hour 48 Part 2-Question B; Yes (n=79)	**68.4**
Hour 48 Part 2-Question B; No (n=79)	**25.3**
Hour 48 Part 2-Question B; Missing (n=79)	**6.3**
Hour 48 Part 2-Question C; Yes (n=79)	**63.3**
Hour 48 Part 2-Question C; No (n=79)	**31.6**
Hour 48 Part 2-Question C; Missing (n=79)	**5.1**
Hour 72 Part 1-Question A; Yes (n=36)	**91.7**
Hour 72 Part 1-Question A; Missing (n=36)	**8.3**
Hour 72 Part 1-Question C; Yes (n=36)	**5.6**
Hour 72 Part 1-Question C; No (n=36)	**52.8**
Hour 72 Part 1-Question C; Partial (n=36)	**30.6**
Hour 72 Part 1-Question C; Missing (n=36)	**11.1**
Hour 72 Part 1-Question D; Yes (n=36)	**86.1**
Hour 72 Part 1-Question D; No (n=36)	**2.8**
Hour 72 Part 1-Question D; Missing (n=36)	**11.1**
Hour 72 Part 2-Question A; Yes (n=36)	**41.7**
Hour 72 Part 2-Question A; No (n=36)	**47.2**
Hour 72 Part 2-Question A; Missing (n=36)	**11.1**
Hour 72 Part 2-Question B; Yes (n=36)	**58.3**
Hour 72 Part 2-Question B; No (n=36)	**30.6**
Hour 72 Part 2-Question B; Missing (n=36)	**11.1**
Hour 72 Part 2-Question C; Yes (n=36)	**61.1**
Hour 72 Part 2-Question C; No (n=36)	**27.8**
Hour 72 Part 2-Question C; Missing (n=36)	**11.1**

No statistical analysis provided for Physician's Evaluation of Participant's Ability to Undergo Physiotherapy or Mobilization

10. Secondary: Comprehensibility of the Information Material (IM): Physician Questionnaire Responses [Time Frame: Hour 72]

Measure Type	Secondary
Measure Title	Comprehensibility of the Information Material (IM): Physician Questionnaire Responses
Measure Description	Physicians were asked to evaluate the IM for fentanyl-ITS (IONSYS) by responding to following questions of a questionnaire: Part2 D- Would you use IONSYS again, E- Would you prefer IONSYS to intravenous patient controlled analgesia (IV PCA); Part3 A- Was IM easy to understand, B- Did IM help you to use system properly.
Time Frame	Hour 72
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.
Efficacy analysis set included all participants who received the study treatment at least once and who had efficacy data for primary parameter after 0 hour Baseline visit. 'N' (number of participants analyzed) signifies participants evaluable for this measure.

Reporting Groups

	Description
Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Measured Values

	Fentanyl
Overall Participants [units: participants]	**36**
Comprehensibility of the Information Material (IM): Physician Questionnaire Responses [units: percent of participants]	
Part 2-Question D; Yes	**83.3**
Part 2-Question D; No	**5.6**
Part 2-Question D; Missing	**11.1**
Part 2-Question E; Yes	**77.8**
Part 2-Question E; No	**11.1**
Part 2-Question E; Missing	**11.1**
Part 3-Question A; Yes	**88.9**
Part 3-Question A; Missing	**11.1**
Part 3-Question B; Yes	**88.9**
Part 3-Question B; Missing	**11.1**

No statistical analysis provided for Comprehensibility of the Information Material (IM): Physician Questionnaire Responses

11. Secondary: Comprehensibility of the Information Material (IM): Nursing Staff Questionnaire Responses [Time Frame: Hour 72]

Measure Type	Secondary
Measure Title	Comprehensibility of the Information Material (IM): Nursing Staff Questionnaire Responses
Measure Description	Nursing staff were asked to evaluate the IM for IONSYS by responding to following questions of a questionnaire: IM A- Was IM easy to understand, B- Did IM help you to use system properly; IONSYS PCA A- Is system easy to handle, B- Did participant need help in using system, C- Do you feel confident using IONSYS; IV PCA- Are you experienced in using IV PCA; IONSYS PCA D- Could participant get mobilized sooner, E- Does participant move more, F- Is participant less afraid of moving, G- Were hospital logistics for IONSYS easier to handle.
Time Frame	Hour 72
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.
Efficacy analysis set included all participants who received the study treatment at least once and who had efficacy data for primary parameter after 0 hour Baseline visit.

Reporting Groups

	Description

Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Measured Values

	Fentanyl
Overall Participants [units: participants]	**170**
Comprehensibility of the Information Material (IM): Nursing Staff Questionnaire Responses [units: percent of participants]	
IM-Question A; Yes	**97.1**
IM-Question A; Missing	**2.9**
IM-Question B; Yes	**95.9**
IM-Question B; No	**1.2**
IM-Question B; Missing	**2.9**
IONSYS PCA-Question A; Yes	**95.3**
IONSYS PCA-Question A; No	**1.8**
IONSYS PCA-Question A; Missing	**2.9**
IONSYS PCA-Question B; Yes	**23.5**
IONSYS PCA-Question B; No	**73.5**
IONSYS PCA-Question B; Missing	**2.9**
IONSYS PCA-Question C; Yes	**90.0**
IONSYS PCA-Question C; No	**5.9**
IONSYS PCA-Question C; Missing	**4.1**
IV PCA-Question; Yes	**84.1**
IV PCA-Question; No	**10.6**
IV PCA-Question; Missing	**5.3**
IONSYS PCA-Question D; Yes	**31.2**
IONSYS PCA-Question D; No	**48.8**
IONSYS PCA-Question D; Missing	**20.0**
IONSYS PCA-Question E; Yes	**52.9**
IONSYS PCA-Question E; No	**32.4**
IONSYS PCA-Question E; Missing	**14.7**
IONSYS PCA-Question F; Yes	**47.6**
IONSYS PCA-Question F; No	**37.6**
IONSYS PCA-Question F; Missing	**14.7**
IONSYS PCA-Question G; Yes	**71.8**
IONSYS PCA-Question G; No	**12.4**
IONSYS PCA-Question G; Missing	**15.9**

No statistical analysis provided for Comprehensibility of the Information Material (IM): Nursing Staff Questionnaire Responses

12. Secondary: Comprehensibility of the Information Material (IM): Participant Questionnaire Responses [Time Frame: Hour 72]

Measure Type	Secondary
Measure Title	Comprehensibility of the Information Material (IM): Participant Questionnaire Responses
Measure Description	Participants were asked to evaluate the IM for IONSYS by responding to following questions of a questionnaire: A- Is IONSYS easy to use, B- Were you able to operate the system by yourself after receiving instructions, C- Have you found button yourself, D- Was pressing button easy, E- Have you heard system's beeps, F- Was IONSYS IM easy to understand, G- Did IM help you to use system, H- Did you have problems falling asleep, I- Could you move easily in

	bed, J- Did system bother you during physiotherapy, K- Do you perceive use of such system as modern treatment standard.
Time Frame	Hour 72
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.
Efficacy analysis set included all participants who received the study treatment at least once and who had efficacy data for primary parameter after 0 hour Baseline visit.

Reporting Groups

	Description
Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Measured Values

	Fentanyl
Overall Participants [units: participants]	**170**
Comprehensibility of the Information Material (IM): Participant Questionnaire Responses [units: percent of participants]	
Question A; Yes	**77.1**
Question A; No	**1.2**
Question A; Missing	**21.8**
Question B; Yes	**77.6**
Question B; No	**1.2**
Question B; Missing	**21.2**
Question C; Yes	**78.8**
Question C; Missing	**21.2**
Question D; Yes	**77.6**
Question D; No	**1.2**
Question D; Missing	**21.2**
Question E; Yes	**72.9**
Question E; No	**4.7**
Question E; Missing	**22.4**
Question F; Yes	**75.9**
Question F; No	**1.8**
QuestionF; Missing	**22.4**
Question G; Yes	**75.9**
Question G; No	**0.6**
Question G; Missing	**23.5**
Question H; Yes	**30.0**
Question H; No	**46.5**
Question H; Missing	**23.5**
Question I; Yes	**60.6**
Question I; No	**17.1**
Question I; Missing	**22.4**
Question J; Yes	**4.1**
Question J; No	**71.2**

Question J; Missing	**24.7**
Question K; Yes	**75.3**
Question K; No	**1.8**
Question K; Missing	**22.9**

No statistical analysis provided for Comprehensibility of the Information Material (IM): Participant Questionnaire Responses

13. Secondary: Post-Operative Phase (PPP33) Quality of Life Questionnaire Score [Time Frame: Hour 72]

Measure Type	Secondary
Measure Title	Post-Operative Phase (PPP33) Quality of Life Questionnaire Score
Measure Description	The PPP33 questionnaire has an overall score and 8 subscales that represent different aspects of the post-operative quality of life: information, autonomy, communication, physical complaints, pain, rest, fear and accommodation. Answers to individual question are scored with values 1 to 4. Summary scores are calculated by adding values for each question. Subscores ranges depend on the number of questions evaluated (2 to 7 questions). The overall score ranges from 1 to 100. Higher scores indicate less pain.
Time Frame	Hour 72
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.
Efficacy analysis set included all participants who received the study treatment at least once and who had efficacy data for the primary parameter after the 0 hour Baseline visit. 'N' (number of participants analyzed) signifies those participants evaluable for this measure.

Reporting Groups

	Description
Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Measured Values

	Fentanyl
Overall Participants [units: participants]	**105**
Post-Operative Phase (PPP33) Quality of Life Questionnaire Score [units: units on scale] Mean (Standard Deviation)	**76.8 (9.4)**

No statistical analysis provided for Post-Operative Phase (PPP33) Quality of Life Questionnaire Score

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	From signing of informed consent until Day 7 after end of treatment
Additional Description	Treatment-emergent are events between first dose of study drug and up to 7 days after last dose that were absent before treatment or that worsened relative to pre-treatment state.

Reporting Groups

	Description
Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Serious Adverse Events

	Fentanyl
Total, serious adverse events	
# participants affected / at risk	**3/174 (1.72%)**
Gastrointestinal disorders	
Intra-abdominal haematoma * 1	
# participants affected / at risk	**1/174 (0.57%)**
General disorders	
Impaired healing * 1	
# participants affected / at risk	**1/174 (0.57%)**
Respiratory, thoracic and mediastinal disorders	
Hypoventilation * 1	
# participants affected / at risk	**1/174 (0.57%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	From signing of informed consent until Day 7 after end of treatment
Additional Description	Treatment-emergent are events between first dose of study drug and up to 7 days after last dose that were absent before treatment or that worsened relative to pre-treatment state.

Frequency Threshold

Threshold above which other adverse events are reported	1

Reporting Groups

	Description
Fentanyl	Fentanyl Iontophoretic Transdermal (through the skin) System (ITS) releasing fentanyl at the rate of 40 microgram (mcg) (1 dose) to maximum of 240 mcg per hour (6 doses) but not more than 3.2 milligram (mg) (80 doses) per 24 hours. The duration of study treatment was up to 72 hours.

Other Adverse Events

	Fentanyl
Total, other (not including serious) adverse events	
# participants affected / at risk	**86/174 (49.43%)**
Blood and lymphatic system disorders	
Anaemia * 1	
# participants affected / at risk	**3/174 (1.72%)**
Haemorrhagic anaemia * 1	
# participants affected / at risk	**2/174 (1.15%)**
Gastrointestinal disorders	

Nausea [*1]	
# participants affected / at risk	**27/174 (15.52%)**
Vomiting [*1]	
# participants affected / at risk	**16/174 (9.20%)**
Flatulence [*1]	
# participants affected / at risk	**3/174 (1.72%)**
Constipation [*1]	
# participants affected / at risk	**2/174 (1.15%)**
General disorders	
Application site erythema [*1]	
# participants affected / at risk	**18/174 (10.34%)**
Application site vesicles [*1]	
# participants affected / at risk	**5/174 (2.87%)**
Application site burn [*1]	
# participants affected / at risk	**4/174 (2.30%)**
Application site irritation [*1]	
# participants affected / at risk	**3/174 (1.72%)**
Application site pruritus [*1]	
# participants affected / at risk	**3/174 (1.72%)**
Application site oedema [*1]	
# participants affected / at risk	**2/174 (1.15%)**
Application site pain [*1]	
# participants affected / at risk	**2/174 (1.15%)**
Injury, poisoning and procedural complications	
Procedural nausea [*1]	
# participants affected / at risk	**4/174 (2.30%)**
Procedural vomiting [*1]	
# participants affected / at risk	**4/174 (2.30%)**
Investigations	
Oxygen saturation decreased [*1]	
# participants affected / at risk	**2/174 (1.15%)**
Nervous system disorders	
Dizziness [*1]	
# participants affected / at risk	**6/174 (3.45%)**
Psychiatric disorders	
Sleep disorder [*1]	
# participants affected / at risk	**2/174 (1.15%)**
Skin and subcutaneous tissue disorders	
Erythema [*1]	
# participants affected / at risk	**5/174 (2.87%)**
Vascular disorders	
Hypotension [*1]	
# participants affected / at risk	**6/174 (3.45%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 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
The study was prematurely discontinued after enrolling 184 of 200 planned participants because the study medication was no longer available.

More Information

Hide More Information

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.

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