A Clinical Trial With Intranasal Fentanyl in Cancer Patients With Breakthrough Pain (NOSE-400)

This study has been completed.

Sponsor:
Takeda

Information provided by (Responsible Party):
Takeda

ClinicalTrials.gov Identifier:
NCT01429051

First received: September 1, 2011
Last updated: February 20, 2014
Last verified: February 2014
History of Changes

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Results First Received: January 1, 2014

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Conditions:	Break Through Pain Cancer
Interventions:	Drug: Intranasal Fentanyl Spray (INFS) 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
Participants took part in the study at 11 investigative sites in Hungary, Norway and Russia from 08 August 2011 to 04 January 2013.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
The first dose of Intranasal Fentanyl Spray (INFS) was taken at the clinic for training purposes and was not related to treatment of a BTP episode. One patient received the initial 50 µg test dose but did not receive INFS for titration, but is included in the safety analysis set.

Reporting Groups

	Description
Intranasal Fentanyl Spray (INFS)	All participants were step-wise titrated to an effective dose of 50, 100, 200 or 400 µg INFS in the Titration

	Phase (I). Participants titrated to 200 or 400 µg INFS in the Titration Phase were randomized to an 8-spray sequence in the Efficacy Phase (II); 6 BTP episodes were treated with 400 µg INFS and 2 BTP episodes with placebo in a random sequence. Participants entered the Tolerability Phase (III) either directly from the Titration Phase (with an effective dose of 50 or 100 µg) or from the Efficacy Phase (400 µg) and continued with this specific dose, unless adjustment was needed, for a total treatment time of 12 weeks.

Participant Flow for 3 periods

Period 1: Titration Phase

	Intranasal Fentanyl Spray (INFS)
STARTED	45
COMPLETED	33
NOT COMPLETED	12
Death	1
Withdrawal by Subject	7
Physician Decision	1
Unsuccessful titration at any dose	1
Less than 3 BTP episodes per week	2

Period 2: Efficacy Phase

	Intranasal Fentanyl Spray (INFS)
STARTED	15 [1]
COMPLETED	13
NOT COMPLETED	2
Adverse Event	1
Death	1

[1] Participants titrated to 200 or 400 µg INFS in Titration Phase

Period 3: Tolerability Phase

	Intranasal Fentanyl Spray (INFS)
STARTED	31 [1]
COMPLETED	16
NOT COMPLETED	15
Death	5
Adverse Event	2
Withdrawal by Subject	5
Physician Decision	1
Other	2

[1] Participants entered directly from the Titration or Efficacy Phase

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.
The safety analysis set included all participants who received at least 1 dose of INFS (including the initial test dose).

Reporting Groups

	Description
Intranasal Fentanyl Spray (INFS)	All participants were step-wise titrated to an effective dose of 50, 100, 200 or 400 µg INFS in the Titration Phase (I). Participants titrated to 200 or 400 µg INFS in the Titration Phase were randomized to an 8-spray sequence in the Efficacy Phase (II); 6 BTP episodes were treated with 400 µg INFS and 2 BTP episodes with placebo in a random sequence. Participants entered the Tolerability Phase (III) either directly from the Titration Phase (with an effective dose of 50 or 100 µg) or from the Efficacy Phase (400 µg) and continued with this specific dose, unless adjustment was needed, for a total treatment time of 12 weeks.

Baseline Measures

	Intranasal Fentanyl Spray (INFS)
Number of Participants [units: participants]	**46**
Age [units: years] Mean (Standard Deviation)	**61.0 (9.09)**
Gender [units: participants]	
Female	**31**
Male	**15**
Race/Ethnicity, Customized [units: participants]	
White	**46**
Region of Enrollment [units: participants]	
Hungary	**33**
Norway	**10**
Russian Federation	**3**
Site of Primary Tumour Reported in >5% Patients [units: participants]	
Breast	**14**
Lung respiratory system	**5**
Gastro-oesophageal	**1**
Colon/rectal	**3**
Pancreas	**6**
Female genital	**3**
Prostate	**3**
Urological	**7**
Unknown Primary Tumour	**2**

Liver	**1**
Other	**1**

Outcome Measures

Show All Outcome Measures

1. Primary: Induction Phase: Pain Intensity Difference at 10 Minutes (PID10) After Treatment [Time Frame: During the efficacy phase (II), at each episode of breakthrough pain, at 0 and 10 minutes after first dose of study drug.]

Show Outcome Measure 1

2. Secondary: Incidence of Improvement or Worsening in Nasal Mucosa Sign or Abnormality Score [Time Frame: Baseline and at 12 weeks]

Show Outcome Measure 2

3. Secondary: Efficacy Phase: Pain Intensity Difference (PID) at 5, 30, and 60 Minutes After First Dose of Study Drug [Time Frame: During the efficacy phase (II) each episode of breakthrough pain, at 0, 5, 30 and 60 minutes after study drug.]

Show Outcome Measure 3

4. Secondary: Efficacy Phase: Sum of Pain Intensity Differences (SPID0-60 and SPID0-30) Derived From PI Scores [Time Frame: During the efficacy phase (II) each episode of breakthrough pain, at 0, 5, 30 and 60 minutes after study drug]

Show Outcome Measure 4

5. Secondary: Efficacy Phase: Proportion of BTP Episodes With a Positive Response Defined as a ≥ 1, 2 or 3 Point Reduction in Pain Intensity [Time Frame: During the efficacy phase (II) each episode of breakthrough pain, at 0, 5, 30 and 60 minutes after study drug]

Show Outcome Measure 5

6. Secondary: Efficacy Phase: Proportion of BTP Episodes With a Positive Response Defined as a ≥ 33% or 50% Reduction in Pain Intensity [Time Frame: During the efficacy phase (II) each episode of breakthrough pain, at 0, 5, 30 and 60 minutes after study drug]

Show Outcome Measure 6

7. Secondary: Efficacy Phase: General Impression (GI) Score at 60 Minutes After First Dose [Time Frame: During the efficacy phase (II), at each episode of breakthrough pain, 60 minutes after first dose of study drug.]

Show Outcome Measure 7

8. Secondary: Number of Participants With Adverse Events (AEs) [Time Frame: 12 weeks]

Show Outcome Measure 8

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

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
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More Information

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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. ☑ **Restriction Description:** The first study related publication will be a multi-center publication submitted within 24 months after conclusion or termination of a study at all sites. After such multi site publication, all proposed site publications and presentations will be submitted to sponsor for review 60 days in advance of publication. Site will remove Sponsor confidential information unrelated to study results. Sponsor can delay a proposed publication for another 60 days to preserve intellectual property.

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Responsible Party:	Takeda
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