

This study is currently recruiting participants.

Verified by Insys Therapeutics Inc, November 2007

Sponsored by:	Insys Therapeutics Inc
Information provided by:	Insys Therapeutics Inc
ClinicalTrials.gov Identifier:	NCT00538863

► Purpose

The purpose of this study is to assess up to 90 days the safety of Fentanyl SL Spray for the treatment of **breakthrough cancer pain** in subjects on around-the-clock opioids for their persistent **cancer pain**

<u>Condition</u>	<u>Intervention</u>	<u>Phase</u>
Cancer Pain	Drug: Fentanyl Sublingual Spray	Phase III

MedlinePlus related topics: [Cancer](#)

ChemIDplus related topics: [Fentanyl Citrate](#) [Fentanyl](#)

U.S. FDA Resources

Study Type: Interventional

Study Design: Supportive Care, Open Label, Single Group Assignment, Safety Study

Official Title: Open-Label Multi-Center Safety Trial of Fentanyl Sublingual Spray (Fentanyl SL Spray) for the Treatment of **Breakthrough Cancer Pain**

Further study details as provided by Insys Therapeutics Inc:

Primary Outcome Measures:

- The primary objective is to assess the safety of Fentanyl SL Spray in subjects on efficacious doses of Fentanyl SL Spray [Time Frame: 90 days]

Secondary Outcome Measures:

- Tolerability Acceptability [Time Frame: 90 days]

Estimated Enrollment: 225

Study Start Date: November 2007

Estimated Study Completion Date: March 2009

Intervention Details:

Drug: Fentanyl Sublingual Spray

Fentanyl Sublingual Spray at 100 mcg, 200 mcg, 400 mcg, 800 mcg, 1200 mcg, or 1600 mcg after titration.

Detailed Description:

This is an open-label multi-center study of the safety of Fentanyl SL Spray as a treatment for breakthrough cancer pain. The study medication is administered under the tongue as a simple spray and can be self-administered by subjects or assisted by their caregivers. In addition, there is a questionnaire assessing satisfaction with the treatment. A total of 300 opioid-treated subjects will be enrolled.

Subjects may enter this study by one of two routes:

- De novo subjects who meet the inclusion criteria and none of the exclusion criteria at the Screening Visit will enroll onto the study at the Open-label Titration Period;
- All subjects who have successfully completed the Double-blind Randomization Period and the Final Visit of Protocol INS-05-001 will be eligible to enter this study as an open-label extension study at the Open label Maintenance Period.

► Eligibility

Ages Eligible for Study: 18 Years and older
 Genders Eligible for Study: Both
 Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

Protocol Number INS-06-007 Amendment 3 – June 4, 2008

All de novo subjects must meet all of the following criteria to be eligible for participation in the study:

1. Male or female, ≥ 18 years of age.
2. Diagnosis of cancer.
3. Opioid tolerant. Patients who are tolerant with opioids are defined as those patients who are taking at least 60 mg of oral morphine/day, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oxycodone/day, at least 8 mg of oral hydromorphone/day or an equianalgesic dose of another opioid for ≥ 7 days for cancer-related pain.
4. Experience persistent pain related to the cancer or its treatment of moderate or lesser intensity in the 24 hours prior to assessment by a verbal rating scale at the Screening Visit.
5. Over the previous seven days, the subject experiences on average one to four breakthrough cancer pain episodes per day usually at least partially controlled by supplemental medication of at least 5 mg immediate-release morphine or an equivalent short-acting opioid (e.g., oxycodone, hydrocodone, or codeine with acetaminophen).
6. Able to evaluate pain relief, assess medication performance, report adverse events (AEs), report use of the study drug or supplemental
7. Able and willing to give informed consent.
8. Women of childbearing potential must have a) a negative urine pregnancy test, b) not be breast feeding and c) agree to practice a reliable form of contraception.

8.2.2 Exclusion Criteria

All de novo subjects who meet any of the following criteria will be ineligible for participation in the study:

1. Intolerable side effects to opioids or fentanyl.
2. Current use of commercially available oral short-acting fentanyl for breakthrough pain. Subjects previously on ACTIQ® or FENTORA® can be enrolled if they have had a seven day washout.
3. Rapidly increasing/uncontrolled pain.
4. A history of major organ system impairment or disease, that in the Investigator's or his/her designee's opinion could increase the risk associated with the use of opioids.
5. Uncontrolled hypertension [systolic blood pressure (BP) \geq 180 mmHg or diastolic BP \geq 90 mmHg on two occasions at least six hours apart] despite antihypertensive therapy, or has a history of hypertensive crisis within the past two years.
6. A recent history (within the past two years) of transient ischemic attacks, neural vascular disease, stroke, or cerebral aneurysms.
7. Clinically uncontrolled sleep apnea.
8. Brain metastases with signs or symptoms of increased intracranial pressure.
9. Inability to assess pain or response to pain medications for any reason, including psychiatric disorder, concurrent medical disorder, or concomitant therapy.
10. Received an investigational study product(s) within 30 days of the Screening Visit.
11. Painful erythema, edema or ulcers under the tongue.
12. Use of monoamine oxidase (MAO) inhibitors within 14 days of the Screening Visit.