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Activity : Abstract
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TITLE:
A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of the Sufentanil NanoTab® PCA System/15 mcg for the Treatment of Post-Operative Pain in Patients after Knee or Hip Replacement Surgery

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AFFIRMATIONS:

Affirmations (Complete):
*: I agree to the above statements
*: Yes
*: No animal subjects were involved in the research
*: Yes, I have IRB or IACUC approval

SESSION CATEGORY:
16.4 REGIONAL ANESTHESIA AND ACUTE PAIN - Pain - Clinical

QUESTIONNAIRE:

Questionnaire (Complete):
Please select: No, do not consider my abstract for the ANESTHESIOLOGY Journal Symposium
Please select: The presenting author is NOT a resident or fellow.
Will you be able to participate in the Resident Research Forum to be held on Saturday, October 12th at 1:00 PM? Not applicable

ABSTRACT:
INTRODUCTION
The Sufentanil NanoTab PCA System (SNPS) is a novel preprogrammed noninvasive product candidate in Phase 3 development that dispenses small (3 mm diameter) sufentanil 15 mcg microtablets sublingually with a 20-minute lockout period. Sufentanil possesses a high therapeutic index with minimal respiratory depressive effects relative to its analgesic effect in animal studies, a low incidence of cardiac instability and minimal pharmacokinetic differences based on age, liver or kidney function. While these attributes could be ideal in a post-operative opioid analgesic, its rapid redistribution from plasma following

IV administration and short duration of action make it less than ideal for intravenous patient-controlled analgesia (IV PCA). IV PCA, particularly with morphine, is associated with limitations, including the use of low therapeutic index opioids, the risk of pump programming errors, venous access failure, and reduced patient mobility from being “chained” to the IV pole.

METHODS

This randomized, double blind, placebo-controlled Phase 3 study was performed as one of two pivotal studies required for FDA approval of SNPS. The study objectives were to compare the safety and efficacy of SNPS to placebo (each with rescue IV morphine available p.r.n.) delivered via the SNPS device for the management of moderate-to-severe post-operative pain after elective unilateral total knee or hip arthroplasty. Up to 440 post-operative inpatients (18 years and older) were to be randomized 3:1 to ensure at least 300 in the SNPS group and 100 in the placebo group, respectively, received study drug, and provided data for analysis. Type of surgery (knee vs. hip) was applied as a stratification factor. The primary efficacy endpoint was the time-weighted sum of pain intensity differences over the 48-hour study period (SPID-48) using an 11-point numerical rating scale. Key secondary efficacy variables included pain intensity and pain relief scores (5-point categorical scale) over the study period, patient global assessments of method of pain control (4-point categorical scale), patient and nurse ease of care scores (using a validated Ease-of-Use questionnaire), and rescue medication consumption. Safety assessments included spontaneous adverse reaction reports, vital signs, medical history, physical examinations, oxygen saturation measurements, and concomitant medication usage. Patients who could not maintain their oxygen saturation (pulse oximetry) at 95% or greater with or without supplemental oxygen were not deemed eligible, and if saturation could not be maintained at this level, were terminated early from the study.

RESULTS

The study was conducted at 35 US sites from August 2012 to April 2013. At the time of this abstract submission, the study was nearing completion. Full data will be available at the time of the meeting and presented in the poster.

CONCLUSION

The Sufentanil NanoTab PCA System may be an attractive alternative to traditional IV PCA analgesia. Based upon prior usability and clinical studies, it is easy for healthcare professionals to set-up and for patients to use. Upon completion of the required studies, a new drug application will be submitted to FDA for review.

SUMMARY:

The Sufentanil NanoTab PCA System, a preprogrammed noninvasive product in development, delivers SL sufentanil 15 mcg tablets with a 20-min lockout. After major orthopedic surgery patients were enrolled in this placebo-controlled postop pain trial. At the time of submission, it was nearly complete. Full results will be presented in the poster.

Status: Complete