Lotus
CLINICAL RESEARCH® LLC

CLINICAL VIGNETTE
FOR PERI-OPERATIVE PAIN TRAINING

Lotus uses several clinical vignettes as part of our peri-operative pain staff training. Below is one example:

Assume the following conditions are true for this hypothetical protocol:

- Post-operative randomization is allowed when the patient has a pain score greater than 4/10 on a visual analog scale and has at least moderate severity on a 4 point categorical scale (0=none, 1=mild, 2= moderate and 3=severe).
- Pre-randomization criteria states that the patient's peri-operative pain must be stable.
- This is an efficacy study with the main efficacy goal being separation of active drug from placebo.

Case # 1) 26 year old female presents for laparoscopic cholecystectomy. Surgery and anesthesia are uneventful. No protocol violations have occurred intra-operatively. Patient enters the recovery room and is clearly agitated. She is difficult to control in the recovery room bed, moving and writhing. Speech is garbled. She reports her pain as 9.5 on a 10 point scale. Her heart rate is 105.

Should the patient be randomized and study medication be administered at this time? Why or why not?

1b) Study staff decides not to randomize and instead to provide the patient with 25 micrograms of IV fentanyl for stabilization of her peri-operative pain. The fentanyl is administered at 8:05 AM. The protocol mandates a 20 minute waiting period after standard of care narcotics prior to reassessment for randomization. At 8:27 AM, the patient is queried as to her pain level. She is now resting comfortably, she says she is doing much better and the pain is subsiding. Her pain score is now 5/10 and moderate in severity. The protocol mandates that the pain must be at least 4/10 and moderate to severe.

Should the patient be randomized at this time? Why or why not?