

PAIN Study Update (SDFD)

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For better or worse...
not this pain study

- Definitely for worse
-



Recent changes – study-wide

Inclusion criteria
broadened to
include HR ≥ 115

- Also met by having a shock index ≥ 0.9

Other inclusion
criteria
unchanged

- Going to UCSD-Hillcrest Trauma
- Pain score 5 or greater (out of 10)

Recent changes - local

PAIN study drug moved from SDFD engines to Falck ambulances

- Not currently IRB-approved for AMR ambulances
- (Technical issue, not a quality or willingness issue)

Overall number of drug kits being increased to account for the move

- Was 26, will go to 60-70

Current enrollment status

CVFD: 2 patients

SDFD: 1 patient

Potential enrollments (March 2026)

28 patients met inclusion criteria in SFD

Of those, 18 also had at least one exclusion criterion (screen fail)

- 7 of these met the shock index inclusion criteria mathematically but not when using the quick-reference card estimates

Of the remaining 10, 8 were with units that did not have study medication

The remaining 2 were missed enrollments



Falck
Mobile Health
San Diego, CA
March 2026

PAIN Study

Prehospital
Analgesia
INtervention Trial



LITES



FALCK

The **PAIN Study** is a 1:1 randomized, double blinded, multicenter, EFIC clinical trial that compares Fentanyl vs. sub-dissociative Ketamine for prehospital pain management.

N = 994 (497/arm)

N = 160 as of March 20, 2026

INCLUSION Criteria

Must Have Heart Rate \geq 115

$$SI = HR \div SBP$$

OR

$$SI = HR \div SBP$$

1. Transport after injury to *UCSD Hillcrest*.

2. *NRS Pain score of 5-10, at time of enrollment.*

3. **Heart Rate of 115 or greater (regardless of blood pressure) OR a Shock Index of at least 0.9 or greater, at *any time* during patient care.**

$$\text{SHOCK INDEX} = \frac{\text{HEART RATE}}{\text{SYSTOLIC BLOOD PRESSURE}}$$

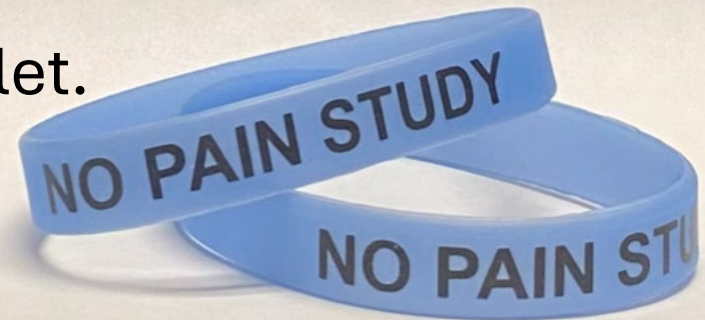
Meet **SI** Criteria in **Green** to Qualify

Shock Index		HEART RATE									
		70	75	80	85	90	95	100	105	110	115 +
S Y S T O L I C	80	0.9	0.9	1.0	1.1	1.1	1.2	1.3	1.3	1.4	✓
	85	0.8	0.9	0.9	1.0	1.1	1.1	1.2	1.2	1.3	✓
	90	0.8	0.8	0.9	0.9	1.0	1.1	1.1	1.2	1.2	✓
	95	0.7	0.8	0.8	0.9	0.9	1.0	1.1	1.1	1.2	✓
	100	0.7	0.8	0.8	0.9	0.9	1.0	1.0	1.1	1.1	✓
	105	0.7	0.7	0.8	0.8	0.9	0.9	1.0	1.0	1.0	✓
	110	0.6	0.7	0.7	0.8	0.8	0.9	0.9	1.0	1.0	✓
	115	0.6	0.7	0.7	0.7	0.8	0.8	0.9	0.9	1.0	✓
	120	0.6	0.6	0.7	0.7	0.8	0.8	0.8	0.9	0.9	✓
	125	0.6	0.6	0.6	0.7	0.7	0.8	0.8	0.8	0.9	✓
	130 +	SBP \geq 130: Only Enroll if HR > 115									✓

* If at any time the HR is \geq 115 or SI is \geq 0.9, patient can be enrolled!

***EXCLUSION* Criteria**

1. **No IO:** Must have IV access.
2. **No Pediatrics:** Cannot be under 18 years old.
3. **No Prisoners:** Transferred from jail or in police custody.
4. **No female patients under 50 years old.**
5. **No SBP *greater* than 180mmHg** at the time of enrollment.
6. **No patients with known allergies** to Fentanyl or Ketamine.
7. **No contraindications** to pain medication **based on local protocols.**
8. **No advanced airway *prior*** to the first dose of study medication.
9. **No objections** to the study by patient or family member.
10. **No Bracelet:** Wearing a “NO PAIN STUDY” opt-out bracelet.



PAIN STUDY

DOES MY PATIENT MEET THE CRITERIA TO ENROLL?

Any Traumatic Injury & Transporting to UCSD- Hillcrest

NO

YES ↓

Male 18 Years & Older
or
Female 50 Years & Older

NO

YES ↓

Pain Score 5-10

NO

YES ↓

SHOCK
Heart Rate
Systolic BP
INDEX

HR 115 or Greater
OR
Shock Index 0.9 or Greater

NO

YES ↓

SBP Greater than 100 &
Less Than 180

NO

YES ↓

NOT Handcuffed or Detained

NO

YES ↓

IV Established?

NO

YES ↓

✓ ENROLL

 DO NOT ENROLL

1ml/10kg, slow IVP over 2-5 minutes.
May repeat in 15 minutes if pain score remains 5 or greater.

Scan QR code on package. Leave package at the ED.

Study Medication Kits and Dosing

- Double-blinded, prefilled syringes of study medication.
- Equal volumes of administration.
- Concentrations selected for weight-based dosing. *Dosing volume is 1ml/10kg.*
- 2 doses per kit. All kits are 100% Fentanyl or 100% Ketamine. *There are no mixed kits!*
- Administered as a slow IV bolus over approximately 2-minutes.
- Maximum of 2 doses per patient.
- A second dose may be administered 15-minutes after the initial dose if the NRS Pain Score remains in the range of 5-10.

DOSING:

Ketamine: 0.25mg/kg

Fentanyl: 1mcg/kg

CONCENTRATION:

Ketamine: 2.5mg/ml

Fentanyl: 10mcg/ml



Patient receives a volume of 1ml/10kg. Max 10ml total volume *per dose.*

Max Ketamine (per dose): 25mg
Max Fentanyl (per dose): 100mcg



PAIN Study Medication

**STERILE ANALGESIC
SOLUTION FOR INJECTION
10 mL Pre-Filled Syringe**

**Ketamine C-III 25 mg/10 mL
(2.5 mg/mL)**

or

**Fentanyl C-II 100 mcg/10 mL
(10 mcg/mL)**

LOT: 12345

EXP: 01/01/1900

Kit Number: 001

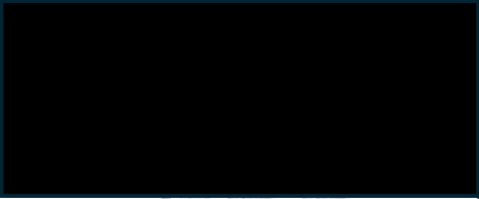
Scan QR Code to
complete study reporting:

**Directions: Administer 0.1 mL/kg IV,
slowly over 2 minutes. Dose may be
repeated after 15 minutes if patient
continues to meet criteria.**

**Date Compounded: 01/01/1900
Store at Room Temperature
Excursions permitted -20°C to 40°C**

**Caution: New Drug - Limited by
Federal (or United States) law
to investigational use.**

**If treatment arm must be known,
call either:**



QR Code and Documentation

- **WASTE ALL UNUSED MEDICATION VIA FALCK POLICY!**
- **Patient transport to UCSD Hillcrest.**
- **After transfer of care at UCSD Hillcrest, the Paramedic *must* scan the QR code on the medication kit packaging and answer the 9 associated questions.**
- **After scanning the QR code, place the study medication packaging in the dropbox at UCSD Hillcrest.**
- **The Paramedic *must* document the *kit number, SI, and NRS Pain Score* in the ePCR.**

The screenshot shows a web-based form titled "LITES PAIN". The form contains the following fields and options:

- Select Pain Trauma Center:** A dropdown menu.
- Select an EMS:** A dropdown menu.
- Name of Medic:** A text input field.
- Brief description of patient (e.g., gender, race, approximate age, etc. Do not include PHI.):** A text input field.
- Did the patient meet all inclusion criteria and not meet any of the exclusion criteria?** Radio buttons for Yes and No.
- Qualifying Pain Measurement used:** A dropdown menu.
- Enter Qualifying Pain Score:** A dropdown menu.
- Record Kit #:** A text input field.
- Was the study drug given according to protocol?** Radio buttons for Yes and No.
- Register** button.

**Please scan the QR
code to mark your
attendance at PAIN
Training!**

*Thank you for your hard work
and dedication to the future of
prehospital emergency
medicine!*



“Be good, be kind, be safe”