MILWAUKEE COUNTY

EMERGENCY MEDICAL SERVICES DIVISION

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NUMBERED NOTICE

Number: **24-05 v2**
Date: **9/25/2024**
From: Ben Weston, MD, MPH, Medical Director
To: All EMS Clinicians
Subject: LITES Study
Purpose: Directive

The LITES Pain study began on Monday, September 9, 2024. This study has seen a handful of patients enrolled already. Below are several brief reminders about process and inclusion criteria:

1. Ensure review of ALL inclusion and exclusion criteria BEFORE opening and administering study drug.
2. The shock index (heart rate / systolic blood pressure) must be greater than 0.9 to be eligible for study drug.
3. Females under 50 are not eligible for study drug.
4. If study drug is administered you MUST scan the QR code on the brown packaging to enroll and track the patient.

Please view the below 2 minute video to review the inclusion and exclusion criteria as well as two very short scenarios to demonstrate patient presentation and medical decision making. That video can be viewed here or by scanning this QR code:

Ben Weston, MD, MPH
Chief Medical Director
Office of Emergency Management

Dan Pojar
EMS Division Director
Office of Emergency Management

LITES SOAR Card v.3

(Study Overview and Reference)

knowledge changing life

LITES Fentanyl vs Ketamine Trauma Pain Trial

Objectives

Compare fentanyl vs ketamine for pain in trauma patients in compensated shock

Inclusion Criteria	***Exclusion Criteria***
• Trauma activation AND transport to FH Level I Trauma Center • Male ≥18; Female ≥50 • Compensated shock index (SI*) > 0.9 • IV Pain med indication (pain scale > 5) • Pain control indicated by Pain Management Practice Guideline *SI = HR/SBP	• Patients without IV access • SBP> 180 mmHg at screening • Contradiction to pain med (hypotensive) • Advanced airway management • Allergy to fentanyl OR ketamine • Potentially pregnant people: Females < 50 • Prisoners: referred from jail or currently in police custody • Wearing PAIN Opt Out bracelet • Voiced objection by patient or family at scene

******DO NOT USE IN CHILDREN UNDER 18 YRS OF AGE OR PREGNANT WOMEN *** MAY BE HARMFUL***

Consent Process

- This is an Exception form Informed Consent (EFIC) study. Prior consent is NOT required. Verbal refusals permitted

Key Steps

- ASSESS inclusion/exclusion criteria
- ADMINISTER dose 1 from kit (save packaging for trauma team)
- SCORE pain level 15 minutes after 1st dose
- ADMINISTER 2nd dose if needed
- TRANSFER PATIENT
- INPUT scan QR code on brown study kit bag and enter patient information
- EMS Providers WASTE remaining drug (into Cactus), document in OPIQ
- Hand empty package to treating team
- DOCUMENT LITES study drug administration, with control #, in ePCR

Key Contact

- Fire Department EMS Liaison
- Study contact – MCW EMS Research Team: litespain@mcw.edu

SHOCK INDEX REFERENCE TABLE

HR ≥ SBP

LITES

Shock Index: Heart rate/Systolic BP

Compensated shock SI > 0.9

Systolic Pressure	Heart Rate 70	80	90	100	110	120	130	140	150	160	170	180
95	0.7	0.8	0.95	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9
100	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8
105	0.7	0.8	0.9	1.0	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7
110	0.6	0.7	0.8	0.91	1.0	1.1	1.2	1.3	1.4	1.5	1.5	1.6
115	0.6	0.7	0.8	0.9	1.0	1.0	1.1	1.2	1.3	1.4	1.5	1.6
120	0.6	0.7	0.8	0.8	0.92	1.0	1.1	1.2	1.3	1.3	1.4	1.5
125	0.6	0.6	0.7	0.8	0.9	1.0	1.0	1.1	1.2	1.3	1.4	1.4
130	0.5	0.6	0.7	0.8	0.8	0.92	1.0	1.1	1.2	1.2	1.3	1.4
135	0.5	0.6	0.7	0.7	0.8	0.9	1.0	1.0	1.1	1.2	1.3	1.3
140	0.5	0.6	0.6	0.7	0.8	0.9	0.93	1.0	1.1	1.1	1.2	1.3
145	0.5	0.6	0.6	0.7	0.8	0.8	0.9	1.0	1.0	1.1	1.2	1.2
150	0.5	0.5	0.6	0.7	0.7	0.8	0.9	0.93	1.0	1.1	1.1	1.2
155	0.5	0.5	0.6	0.6	0.7	0.8	0.8	0.90	1.0	1.0	1.1	1.2
160	0.4	0.5	0.6	0.6	0.7	0.8	0.8	0.9	0.94	1.0	1.1	1.1
165	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.8	0.91	1.0	1.0	1.1
170	0.4	0.5	0.5	0.6	0.6	0.7	0.8	0.8	0.9	0.94	1.0	1.1
175	0.4	0.5	0.5	0.6	0.6	0.7	0.7	0.8	0.9	0.91	1.0	1.0
180	0.4	0.4	0.5	0.6	0.6	0.7	0.7	0.8	0.8	0.9	0.94	1.0

Research

LITES RESEARCH PATHWAY
Practice Guideline

LITES STUDY DRUG

LITES STUDY DRUG	ADULT DOSE	PEDIATRIC DOSE	ADMINISTRATION GUIDELINE	INDICATIONS	CONTRA-INDICATIONS	MACC
Trauma Analgesia **IV** SLOW PUSH	**0.1 mL/kg** Max single dose 10 mL	Not indicated for age <18 yrs	IV Route only Volume-based dosing Up to two doses per pt Blinded to receive *either* Fentanyl or Ketamine	Acute trauma Pt meets criteria for LITES study enrollment	Age < 18 yrs Female < 50 yrs Pain score ≤ 5 Shock index ≤ 0.9 Complete exclusion criteria listed in PG LITES Research Pathway	✓
	Concentration: supplied in 10 mL syringes (*blinded* Fentanyl *or* Ketamine)					

Trauma Analgesia (LITES study)	Weight (kg)	40	45	50	55	60	65	70	75	80	85	90	95	100
	Volume (0.1 mL/kg)	4 mL	4.5 mL	5 mL	5.5 mL	6 mL	6.5 mL	7 mL	7.5 mL	8 mL	8.5 mL	9 mL	9.5 mL	10 mL