REGEN MED

# ARTICLE

## PHASE IV CLINICAL TRIAL CIRCLE: KETAMINE INFUSION FOR POST OPERATIVE PAIN

## CLINICALTRIALS.GOV ID NCT 06066879

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**ABSTRACT:** This Circle will aggregate data to help determine whether a pre-operative ketamine infusion can provide a decrease in post-operative analgesic and opioid consumption similar to that of intra-operative ketamine. The post-operative monitoring period will extend through ninety days. The trial hypothesis is that pre-operative ketamine infusion will lead to a decrease in narcotic consumption from baseline following an elective cervical or lumbar fusion, leading to increased functionality and quality of life.

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## BACKGROUND

Patients with chronic pain requiring daily opioid use often rely on invasive surgeries for long-term pain management. Nevertheless, many still require opioid pain medications, as well as increased use, during the immediate post-operative phase.

For patients with chronic neck or back pain, choosing to undergo invasive spinal surgeries could provide some relief of daily pain. There is however a chance that they will still require daily narcotics for pain relief post-operatively.

Ketamine, an N-methyl-D-aspartate receptor antagonist, has received renewed attention for its ability to provide anesthesia in patients with chronic and neuropathic pain syndromes. Recent studies have shown evidence that intra-operative delivery of ketamine can reduce acute post-operative analgesic consumption following various surgical procedures, though this is often focused on the acute post-operative period (initial 72 hours).

Studies have also shown that ketamine infusions in patients with chronic pain requiring opioid analgesics does provide some variable level of baseline pain improvement.

Peri-operative ketamine infusion has been shown to decrease post-operative pain from surgeries such as cervical and lumbar fusions. There is also evidence that ketamine infusions in general can help to improve levels of chronic pain, reducing the need for opioid medications.

## STUDY DESIGN

### General

Dr. Jennifer Jameson practices at the Axis Spine Center, part of the Northwest Specialty Hospital. She has been the principal investigator on a number of clinical trials in anesthesiology and interventional pain management.

Dr. Jameson's Circle supporting the clinical trial which is the subject of the present article reflects the following principal components:

- IRB-approved and monitored.
- Site: Axis Spine Center.
- Non-Randomized Cohort Study. Interventional/treatment. Open label. Parallel assignment.
- Conditions: revision spine surgery, fusion of spine, cervical fusion, lumbar fusion.

- Estimated Enrollment: 40.

## Inclusion Criteria

- Male or female aged 18-75.
- Able to understand the informed consent form and provide written informed consent and able to complete outcome measures.
- Stated willingness to comply with all study procedures and availability for the duration of the study.
- Daily opiate use totaling ≥50 morphine milli-equivalents (MME) or more for 6 weeks or greater.
- Scheduled for revision surgical fusion of the cervical or lumbar spine.
- Total duration of neck or back pain >12 weeks.

## Exclusionary Criteria

- Current use of Ketamine for any other medical conditions.
- Uncontrolled hypertension.
- Uncontrolled diabetes.
- Increased intracranial pressure.
- Pregnancy or lactation.
- Known allergic reactions to components of ketamine or midazolam.
- Participants who ultimately require intra-operative ketamine administration for anesthesia.
- Treatment with another investigational drug or other intervention within 12 months of study treatment.
- History of psychosis or schizophrenia.
- History of conversion disorder.
- History of clotting disease.
- Pending or active compensation claim, litigation or disability remuneration (secondary gain).
- Surgically naïve patients.
- Allergies to any of the medications to be used during the procedures.
- Active infection or systemic or localized infection at needle entry sites (subject may be considered for inclusion once infection is resolved).
- Uncontrolled immunosuppression (e.g. AIDS, cancer).
- Participating in another clinical trial/investigation within 30 days prior to signing informed consent.
- Subject unwilling or unable to comply with follow up schedule or protocol requirements.

## Primary Outcome Measures

Degree of reduction in opiate consumption following surgery, twelve-week time frame.

## Secondary Outcome Measure

The proportion of subjects who experience at least 50% reduction in back pain

intensity (improvement in ODI scores) at 3 months as compared with baseline.

### More Information On The Trial

ClinicalTrials.gov.

## CIRCLES FOR CLINICAL TRIALS

### General

Circles are an ideal platform for complex clinical trials, as well as simpler studies and registries. They are based on a powerful technology platform with excellent user experience for investigators and patients.

Circles are efficient, low-cost, and highly scalable. They are used by large provider groups, sole practitioners, medical societies, product manufacturers, veterinarians, researchers, and other healthcare constituencies around the world.

### Technology Platform and Processes

Circles utilize the clinical grade [1] and patented [2] clinician-facing inCytes™ and patient-facing Benchmarc™ platforms. This technology is competitive with much more expensive clinical research software.[3]

Circles processes include patient enrollment, long-term outcomes capture, report generation, publication, co-investigator administration, single and multi-center capabilities, publication, industry funding, IRB support and other integrated capabilities.

Circles emphasize patient engagement, comprehension of medical conditions and proposed treatment paths, and long-term compliance.

### Investigator Recruitment and Trial/Study Expansion

Circles support the identification, onboarding, and active involvement of investigators as well as scientific, statistical, and other experts required by the study protocol. As Circle Members, those investigators collaborate within and across institutional and national borders. Circle Hours [4], Circle Academies, and other integrated processes sustain that collaboration.

Often, trial sponsors and/or principal investigators wish to extend a trial's scope, duration and/or other parameters, without compromising the integrity of its original design. The inherent flexibility of Circles accommodates individual investigator variations, additional endpoints, extension of termination dates, and larger or different patient cohorts.

### Supporting The Culture of Research In Academic Medical Centers

Academic medical centers encourage the involvement of clinicians in trials and other forms of medical research. However, internal processes and platforms are often unnecessarily complex and time consuming, seriously undermining those efforts.

Circles combine clinical grade functionality with excellent user experience for all relevant constituencies. They substantially expand the research, education, and training potential of trials and studies at larger hospital systems.

### Democratizing Medical Research

Regulators, legislative bodies, and payers recognize the potential of real-world evidence to improve healthcare outcomes and reduce costs. [5] This has led to a proliferation of registries [6] and study designs -- pragmatic, quality improvement, observational, and other. [7] A corollary is the requirement for more inclusiveness and diversity in clinical trial design. [8]

These developments are the result of broad demand for faster, less expensive pathways to market for medical products, as well as more evidence-based standards of care. [9]

Clinically relevant and statistically significant trials and other forms of studies should not be the sole province of well-capitalized product manufacturers and large hospital systems. Circles put them within reach of small medical practices.

### Further Information On Circles

Circle Overview

Circles/General

KnowledgeBase

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## CONCLUSION

Dr. Jameson's ketamine clinical trial uses integrated technical platforms and processes to achieve the impact of much more expensive clinical trials in an efficient and low-cost manner. Moreover, the initial clinical and scientific value of her trial will likely be significantly amplified through the inherent international collaborative functionality of Circles.

## FOOTNOTES

1 HIPAA, GDPR, Part 11, FHIR HL7 Compliant. Scalable. All data and edits fully auditable. Multilingual. Real-time 24/7 accessibility by patients and clinicians from any device in any location. Robust role, permission, clinician branding, and other customization settings

2 U.S. patent number 11720567, *Method and System For Processing Large Amounts Of Real-World Evidence*.

3 HIPAA, GDPR, Part 11, FHIR HL7 Compliant. Scalable. All data and edits fully auditable. Multilingual. Real-time 24/7 accessibility by patients and clinicians from any device in any location. Robust role, permission, clinician branding, and other customization settings.

4 Regular livestream and recorded sessions among Circle Members reviewing observations, best practices, study variations and emerging correlations.

5 See for example FDA, Real World Evidence, FDA, Post-Market Surveillance Programs; The 21st Century Cures Act; NIH Grants Program For Real-World Studies; Expect To See More RWE-Based Regulatory Decisions, Robert Califf, FDA Commissioner; Use Of Real-World Evidence In Regulatory Decision Making, European Medicines Agency.

6 See Registries for Evaluating Patient Outcomes: A User's Guide: 4th Edition, Agency for Healthcare and Quality and Research, U.S. Department of Health and Human Services.

7 See Pragmatic Trials, NEJM, Ford and Norrie, Quality Improvement Projects and Clinical Research Studies, Faiman, and Quality Improvement In Practice, Backman.

8 See for example, Diversity and Inclusion In Clinical Trials, NIH; Why Diverse Clinical Trial Participation Matters, Schwartz et al, New England Journal Of Medicine.

9 See Transforming Medicare Coverage: A New Medicare Coverage Pathway for Emerging Technologies and Revamped Evidence Development Framework, Fleischer et al., Center For Medicare and Medicaid Services; Center For Clinical and Translational Science/Product Development Pathways, Mayo Clinic. What Is The Evidence For Our Standards Of Care?, Turka et al, The Journal Of Clinical Investigation.