

Percutaneous Auricular Neuromodulation following Total Knee Arthroplasty: A Randomized, Double-Masked, Sham-Controlled Pilot Study

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Introduction

- Neuromodulation: the alteration of nerve activity through targeted delivery of a stimulus, such as electrical stimulation
- Percutaneous auricular neuromodulation involves the percutaneous implantation of multiple leads on/around the ear followed by the delivery of electric current using an external pulse generator.
- Cleared by the US FDA to reduce symptoms associated with opioid withdrawal for up to 5 days
- Stimulator adhered to skin

Methods

- One enrolling center (clinicaltrials.gov 05521516)
- Participants: Adults undergoing primary, unilateral, total knee arthroplasty received a device with three percutaneous leads and one ground electrode
- Randomized postop in recovery room: either active stimulation or sham in double-masked fashion
- Lead removed by patients at home on post-op day 5
- Data collection by phone postop days 1-8
- Primary outcomes: (1) cumulative opioid consumption first 5 days; (2) average NRS of first 5 days
- To claim percutaneous auricular neuromodulation is effective, at least one outcome had to be superior with the other at least noninferior



Results

- N=30 [Ilfeld. *Reg Anesth Pain Med*, In Press]
- Median [IQR] opioid consumption 1st 5 days: active **4 mg** [2, 12] versus **13 mg** [5, 23] for sham (P=0.039)
- Median [IQR] “average” NRS 1st 5 days: active **2.5** [1.5, 3.3] versus **4.0** [3.6, 4.8] for sham (P=0.014)

Conclusions

- Percutaneous auricular neuromodulation reduces pain scores, opioid requirements, and decreases pain’s interference with physical and emotional functioning disturbances during the first week after total knee arthroplasty

