

# Cannabis for Management of Chronic Spine Pain

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# Overview of Presentation

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- Cannabis use in Colorado Spine Patients
- State-funded study
  - Background
  - Study Aims & Design
  - Status
  - Future Studies



# Background

- Patients were increasingly reporting use of cannabis to self-medicate for their spine pain
- 2012: Survey of 184 patients presenting to UCH Spine Clinic
  - 19% reported cannabis use for pain control
  - Users: 44 yo (18-84)
  - Non-users: 54 yo (18-87)
  - 68% had spine condition >1 year
- Method of use
  - Smoke plant material: 45%
  - Smoke + Edibles: 19%
  - Smoke + Vaporize: 10%
  - Smoke + Vaporize + Edibles: 10%



# Background

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## Pain Efficacy

- 85%: moderately/very much relieved pain

## Cannabis vs Other Pain Medications

- 77%: better/equal to NSAIDS
- 77%: better/equal to opioids
- 86%: better/equal to nerve-targeted medications (Lyrica, Neurontin)



# Background

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- Historically, most clinical trials of cannabinoid-based drugs have focused on cancer pain
- 8 RCTs studied smoked (4) or vaporized (4) cannabis vs placebo for neuropathic pain (diabetic/peripheral neuropathy, spinal cord injury/disease)
  - All showed significant improvement pain
  - No serious adverse events
- No evidence for cannabis use in chronic spine pain...




# “Expert” Evidence on Cannabis

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re | <https://cannabis.net/blog/medical/the-top-5-strains-for-chronic-back-pain>

REDcap University of Colorado Health Sciences Library PharmaSchool Clinic RSS Virtual EMS Morphine Equivalent UCHealth



## Top 5 Cannabis Strains For Chronic Back Pain

cannabis strains for back pain

### The Top 5 Strains For Chronic Back Pain

Back Pain and Marijuana Strains To Try Today

Posted by DanaSmith on Friday Feb 10, 2017



# CDPHE-Funded Study

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- RCT (double blind)
- 2 cohorts of subjects:
  - 50 Chronic Back/Neck Pain
  - 50 Healthy Controls
- Study drugs:
  - Cannabis (4-8 puffs of 5% THC; expected range 4.5-5.4%)
    - Flexible dosing scheme: Self-titrate to achieve desired balance of drug effect vs side effects
      - Twice as likely to observe significant differences between placebo and active drug
      - Reduce AE's from supratherapeutic dosing
  - Oxycodone hydrochloride, immediate release (5 or 10 mg)
  - Placebo cannabis (cannabinoids extracted via ethanol)
  - Placebo oxycodone





# CDPHE-Funded Study

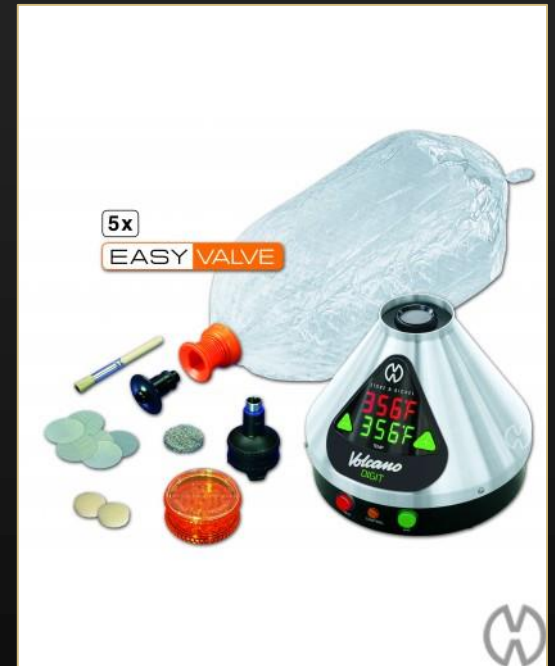
- Cannabis: National Institute on Drug Abuse (NIDA) source grown at U of Mississippi
  - 1970's
  - 2015: NIDA renewed \$68.8 million dollar contract
  - Indoor grow rooms & outdoor Cannabis Garden





# CDPHE-Funded Study

- Vaporization
  - Allows active cannabinoid vapors to form
  - Does not heat to the point of combustion (i.e. release of toxins)
  - Little if any increase in exhaled carbon monoxide after vaporization
  - However, effects on pulmonary outcomes have not been studied



# CDPHE-Funded Study

Subjects come in for 3 separate 4-hour study visits

Vaporized  
**Cannabis**  
+  
Placebo pill

Vaporized  
Placebo  
+  
**Oxycodone** pill

Vaporized  
**Placebo**  
+  
**Placebo** pill



# CDPHE-Funded Study

## Primary Study Aims:

Effect of Study Drugs on:

1. Relief of back and neck pain  
(spine patients)
2. Sensitivity to experimentally-  
induced pain  
(healthy controls)



# CDPHE-Funded Study

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## Secondary Study Aims:

### Effect of Study Drugs on:

1. Patient's global impression of changes in their chronic spine pain condition
2. Subjective reports of drug, psychoactive and mood effects (feeling high, impaired, confused, anxious, nauseated, good drug effect, bad drug effect, etc.)
3. Tests of neurocognitive functioning (attention, concentration, memory, fine motor control)
4. Standardized Field Sobriety Tests
5. AE's



# Regulatory Approvals & Status of Study

- University and Hospital Support
  - Study drug storage room with high level security: keyless code entry, security cameras inside & outside room, padlocked freezer with keyed drug boxes inside, double-locked narcotics cabinets
  - Study drug administration room renovated to included HVAC system
  - 18 months
- Local Regulatory Approvals
  - Scientific Advisory and Review Committee (SARC) approved scientific merit: 3 months
  - IRB (COMIRB): 1 month
- FDA approval of IND: 1 month
- DEA approval of Schedule I/II registrations
  - 6 months for approval, 8 months to get valid registrations
- NIDA approval for cannabis request



# Regulatory Approvals & Status of Study

27 months

Grant Award



Receipt of Cannabis Product





# Status of Study

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- Currently enrolling:

- Phone Screens: 74

- 64 fails: frequent cannabis use, other pain/medical conditions
    - 10 passes



- Screen Visits: 8

- 7 fails: abnormal lab result, psychiatric condition, other pain condition
    - 1 pass



- Study Visits: 1 scheduled



# Future Studies/Considerations

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- Extended use of study drugs
- Transition from opioids alone to opioids + cannabis, or cannabis alone
- Other cannabinoids
  - CBD
  - THC/CBD
- Other preparations
  - Extracts
  - Creams/Patches
  - Edibles??

