CANNABIS OIL AND RADIATION THERAPY
FOR THE MANAGEMENT OF PAIN

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MASCC/ISOO Annual Meeting on Supportive Care in Cancer
Vienna, June 29\textsuperscript{th} 2018
## Faculty Disclosure

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INTRODUCTION
Prevalence of Cancer pain

18.7% to 21.4% of people with cancer have cancer-related neuropathic pain, as a result of either the disease or its treatment.

Single dose of 8gy has become the gold-standard treatment with approximately 60% response rate.

Estimated 31% of cancer patients receiving radiation therapy will experience neuropathic pain as a result.

Gomez-Iturriaga, A. et. al: Incidence of pain flare following palliative radiotherapy for symptomatic bone metastases: multicenter prospective observational study BMC Palliative Care 2015: 14:48
INTRODUCTION

Standard of care

In two observational study average of 40% (37.7, 41.3 respectively) participants experienced a pain flare up post-RT treatment, defined as

• 2-points or more on NRS scale with no analgesic increase; or
• no increase with 25% increase in analgesics

• Average was 3 days post-treatment
• Average duration of flare 1.5 days
• Approx. 25% of patients more than one pain flare

Westoff et al. BMC Cancer 2014, 14:347
INTRODUCTION
Cannabinoids for treatment of cancer-related pain

CONCLUSION:
1.08:1 THC:CBD extract significant effect against pain intensity, but not THC extract
Tolerability, dose-limiting 1.08:1 extract of THC:CBD better tolerability than THC extract
INTRODUCTION

Cannabinoids and radiotherapy

**CONCLUSIONS:** HNC patients report MM use to help with long-term side effects of radiotherapy.

**CONCLUSION:** At the dosage used, nabilone was not potent enough to improve the patients' quality of life over placebo.
INTRODUCTION

Literature

PubMed Article Search

“Cannabinoids” : 18 182

“Cannabinoids” + “Pain” : < 1200

“Cannabinoids” + “Cancer Pain” : < 200

“Cannabinoids” + “Radiotherapy” : 5
INTRODUCTION

Future Directions?

Enhancing the Therapeutic Efficacy of Cancer Treatment With Cannabinoids

Sayeda Yasmin-Karim, Michele Moreau, Romy Mueller, Neelam Sinha, Raymond Dabney, Allen Herman and Wilfred Ngwa

Radiation Oncology, Brigham and Women’s Hospital, Boston, MA, United States; Dana-Farber Cancer Institute, Boston, MA, United States; Harvard Medical School, Boston, MA, United States; University of Massachusetts Lowell, Lowell, MA, United States; University Medical Center Mannheim, Heidelberg University, Mannheim, Germany; Cannabis Science, Inc., Irvine, CA, United States

The Combination of Cannabidiol and Δ⁹-Tetrahydrocannabinol Enhances the Anticancer Effects of Radiation in an Orthotopic Murine Glioma Model

Katherine A. Scott, Angus G. Dalgleish, and Wai M. Liu

DOI: 10.1158/1535-7163.MCT-14-0402 Published December 2014


Nanoparticle Drones to Target Lung Cancer with Radiosensitizers and Cannabinoids

Ngwa W, Kumar R, Moreau M, Dabney R, Herman A

CANNABIS OIL AND RADIATION THERAPY FOR THE MANAGEMENT OF PAIN: ASSESSMENT OF SAFETY AND EFFICACY IN A RANDOMIZED, DOUBLE-BLIND PLACEBO-CONTROLLED PHASE II/III CLINICAL TRIAL

STUDY OBJECTIVE

To demonstrate enhanced pain control of cannabis oil as an adjuvant to palliative radiation therapy (RT) for metastatic breast, lung and prostate cancer, compared to palliative RT alone.
WHERE TO START?

MEDICAL CANNABIS?
Dried cannabis, oral extracts, topical, etc
~ 113-124 "phytocannabinoids"
- Terpenoids, flavanoids
* THC and CBD = Primary cannabinoids

SYNTHETIC CANNABINOIDS?
Dronabinol, Marinol
THC and THC-Analogue

Limited efficacy, tolerance

WHERE TO START?

NABIXIMOLS?

THC
Intoxicating
Analgesic
Anti-emetic
Anti-spasmodic

CBD
Non-intoxicating
Anti-epileptic
Anti-inflammatory
Mild Analgesic

Anxiolytic
Orexigenic
Anxiolytic (bi-phasic)
Sleep Aid (bi-phasic)

Anti-spasmodic
Anti-psychotic

Complex, limited evidence

Limited efficacy, tolerance

METHODS

Study Design

• 6-weeks study period followed by an open-label extension phase of 12 weeks
• Consecutive adult patients with metastatic lung, breast or prostate cancer between the ages of 18 and 75, male and female
  • Referred for palliative RT and with cancer pain of at least 1 month in duration
  • with an average weekly pain intensity score greater than 4 on the 11 points NRS
• Screening, randomization to cannabis oil or placebo
• Treatment initiated 1 week prior to first dose of RT

Product: Cannabis oil capsule PPP-005 (oral) vs placebo
  Low dose: 1mg THC and 1mg CBD
  High dose: 2.5mg THC and 2.5mg CBD
METHODS

Key Exclusion Criteria

• Regular consumption of cannabis or prescribed cannabinoids
• No limitation with respect to number of metastases (bone and visceral);
• Location of metastases limited to exclude any brain metastases
• Karnofsky performance score (KPS) of < 60;
• Patients taking opioid medications must have stable dose at least 15 days
• Abnormal cognitive, liver or renal function
METHODS

* Outcome measures at baseline, 1-week, 3-week and 6-week follow-up.

Primary
- Numeric Pain Rating Scale
- Brief Pain Inventory (BPI-SF)

Secondary
- Symptom burden – (ESAS-r-CS)
- Health-related Quality of Life (EQ-5D-5L)
- FACT-P
- Brief Fatigue Inventory
- Safety: standardized blood samples
- AEs questionnaire
- Mini-Cog
- Profile of Mood States (POMS)
- Hamilton Rating Scale for Depression (HAM-D)
- Medication Quantification Scale (MQS) version III
CONCLUSION

Sample size of 400 patients required, study to start September 2018

CONTACT US
To become a recruitment site: