ISRCTN29199098 https://doi.org/10.1186/ISRCTN29199098

Efficacy of a topical cannabinoid preparation in decreasing symptoms of rheumatoid arthritis.

Submission date
04/03/2014

Recruitment status
No longer recruiting

Registration date
09/04/2014

Overall study status
Completed

Last Edited
09/04/2014

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
In the past ten years, there have been major developments in the use of cannabis and its derivatives (called cannabinoids) for a variety of problems such as gastrointestinal function, nausea and vomiting, pain relief and depression. Studies show that cannabinoids can achieve the following: treatment of pain symptoms with fibromyalgia and neuropathic pain, reducing spasticity in multiple sclerosis, alleviating psychotic symptoms of schizophrenia and treatment of gastrointestinal inflammation due to Crohn's disease. In 2006, the first study using a cannabis-based medicine to treat pain caused by rheumatoid arthritis found significant improvements in pain but the effect size was small and variable across the sample population and further studies are required. As usual pain relief medications for all the conditions described above are often associated with potential harmful side effects, exploring less toxic pain killers is needed. This study will assess whether a topical cannabinoid preparation (cream) applied to the affected finger joints on the hands of individuals with rheumatoid arthritis can significantly reduce joint pain and whether this leads to increased physical mobility and improved quality of life.

Who can participate?
Individuals who have been diagnosed with rheumatoid arthritis who are between the ages of 21 and 75.

What does the study involve?
Participants will be given a numbered informed consent form to read and sign. Using the number on the consent form they will be allocated to one of two treatments (active dose or placebo dose) via a computer generated random number sequence. Expected duration of the participation after screening is 12 weeks. A number of measures will be taken and questionnaires will be filled at several milestones during the study. As it likely that some participants will be on standard medication for their active arthritis, their treatment regime will need to be stable for at least 30 days prior to actual participation in study. All participants will be asked to self-report their experience of finger joint pain at rest on a scale from 0 10, where the higher number indicates more pain, prior to the application of the topical cannabinoid preparation and, again, 10 minutes following each application. Participants in either the active dose and the placebo dose conditions will be asked to apply a topical cream preparation on two or three of the most affected finger joints on each hand three times daily. Participants will be

instructed to measure 0.2ml of cream from the syringe onto the affected finger joint and massage in well, for approximately one minute, until the cream is completely absorbed into the skin. This will be repeated for each affected joint. Maximum total daily dose will be 5ml of cream. The participant should not use more than 100ml of cream for the two three-week phases of this study.

What are the possible benefits and risks of participating?
Participants will be providing information that will show the effects of a topical cannabinoid cream preparation for the treatment of pain experienced with rheumatoid arthritis. There may or may not be direct medical benefit to participants. Those in the active treatment dose may experience pain relief from joint pain. It is hoped that the information learned from the study will benefit other individuals with rheumatoid arthritis in the future.
A review of previous studies of cannabinoids for the treatment of chronic non-cancer pain indicated no serious adverse effects according to the Health Canada definition and the most common adverse events consisted of sedation, dizziness, dry mouth, nausea, and disturbances in concentration. The one possible anticipated risk to the use of the topical cannabinoid preparation is for the participant to develop a skin reaction or some swelling. If this does occur, participants will be advised to discontinue use of the topical preparation immediately and to inform the investigators. They will inform the participants primary doctor who, with the investigators, will then provide ongoing monitoring of the reaction until the adverse reaction has resolved or is stabilized.

Where is this study run from?
Medicinal Cannabis Resource Centre Inc (MCRCI) in Vancouver, BC, Canada. All data at the start of the study will obtained at MCRCI. Data obtained at midpoint, end and follow-up may be obtained from the participant's home or MCRCI, whichever is more convenient for the participant.

When is the study starting and how long is it expected to run for?
The study is ecpected to start in June 2014 and will run for 12 weeks or until the required number of 34 participants have completed the study.

Who is funding the study?
The principle investigator of the study, Dr. Cara Zaskow, is receiving funding through a paid educational leave at Capilano University, Psychology Department, to conduct this study. Other costs affiliated with the study are also being supported by the Medicinal Cannabis Resource Centre Inc (MCRCI), Canada.

Who is the main contact?
Dr. Cara Zaskow
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Efficacy of a topical cannabinoid preparation in decreasing symptoms of rheumatoid arthritis: a randomized, double-blind, placebo-controlled pilot study

Study objectives
The primary objective of this clinical pilot trial is to investigate whether a topical cannabinoid preparation applied to the affected finger joints on the hands of individuals with rheumatoid arthritis can provide a significant analgesic effect resulting in the reduction of joint pain at rest. Secondary objectives include a determination if a reduction of pain is followed by increased mobility in the hand an improved quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomized double-blind placebo-controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
Participants in either the active dose (7.5 grams of finely ground plant material per 100 ml of transdermal cream = 0.94% cannabinoid) and the placebo dose conditions will be asked to apply the cream to two or three of the most affected finger joints on each hand three times daily. Participants will be instructed to measure 0.2ml of cream from the syringe onto the affected finger joint and massage in well, for approximately one minute, until the cream is completely absorbed into the skin. This dosing regimen will be repeated for each affected joint. Maximum total daily dose will be five milliliters (5ml) of cream. The participant should not use more than 100ml of cream for the two three-week phases of this clinical trial.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary endpoint assessed will be daily pain experience as self-reported by the participants measured by a 0 10 Numeric Rating Scale (NRS) 10 minutes following the application of the topical cream preparation (either active dose or placebo dose). The daily NRS rating will be then be averaged for measurements points obtained at midway through the 6 week clinical trial, at the end of the clinical trial and finally at 2 week follow-up.

Secondary outcome measures
Secondary endpoints will include:
1. Assessment of functional status using scores on the Stanford Health Assessment Questionnaire (HAQ, full version, Fries, Spitz, Kraines & Holman, 1980). This is a self-administered, 41 item measure that contains 8 categories which review a specific function evaluating difficulty with activities of daily living (e.g., dressing, grooming, arising, eating, walking, hygiene, errands and chores) over the past week. Also identified are specific aids or devices utilized for assistance such as help needed from another person.
2. Assessment of self-reported activities of daily living and quality of life as measured by the Rheumatoid Arthritis Quality of Life (RAQL, De Jong, van der Heijde, McKenna & Whalley, 1997). This is a self-administered 30 item measure that is answered on a yes/no basis.
3. In addition two measures of physical function developed by Escalante, Hass, and Del Rincon (2004) will be used to provide reproducible, quantitative and objective information about the individuals current level of functional strength and dexterity. One, Grip Strength measured with a device such as a hand-held dynamometer (digital versions available). In a sitting position, with the elbow held at 90 degrees and the forearm supported on a flat horizontal surface, the person

is asked to squeeze the handle with as much strength as possible. Three repetitions for each hand will be obtained and the mean value for all repetitions for each hand will be recorded. The second measure of physical function is the Timed Button Test in which the participant is asked to wear a standard 8 button men's or women's extra large shirt and fasten the front buttons. Stop watch timing is activated from the moment the person takes the shirt and is stopped when all the buttons have been fastened. Measurements for all the secondary endpoints are to be obtained at baseline, midway through the 6 week clinical trial, at the end of the clinical trial and finally at 2 week follow-up.

Overall study start date
02/06/2014

Completion date
01/12/2014

Eligibility

Key inclusion criteria
Males and females between the ages of 21 75 with a diagnosis of rheumatoid arthritis of the proximal interphalangeal joints that is not adequately controlled by standard medication and remain symptomatic.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
34

Key exclusion criteria
1. A history of psychiatric disorders or substance misuse
2. Severe cardiovascular
3. Renal of hepatic disorder
4. A history of epilepsy
5. Recreational or medicinal use of cannabis within the last 6 months

Date of first enrolment
02/06/2014

Date of final enrolment
01/12/2014

Locations

Countries of recruitment

Canada

Study participating centre
Psychology Department
North Vancouver
Canada
V7J3H5

Sponsor information

Organisation
Medicinal Cannabis Resource Centre Inc (Canada)

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Sponsor type
Research organisation

Funder(s)

Funder type
University/education

Funder Name
Capilano University, Psychology Department (Canada)

Funder Name
Medicinal Cannabis Resource Centre Inc. (Canada)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration