ISRCTN49884134 https://doi.org/10.1186/ISRCTN49884134

Naturopathic Treatment of Rotator Cuff Tendonitis Amongst Postal Workers, a randomized controlled parallel group study

Submission date
15/02/2007

Recruitment status
No longer recruiting

Registration date
28/03/2007

Overall study status
Completed

Last Edited
26/03/2021

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Orest Szczurko

Contact details
353 Thrace Ave
Mississauga
Ontario
Canada
L5B 2B2

Additional identifiers

Protocol serial number
03

Study information

Scientific Title
Naturopathic Treatment of Rotator Cuff Tendonitis Amongst Postal Workers, a randomized controlled parallel group study

Acronym
NTRCTAPW

Study objectives
This study aims to evaluate the difference in efficacy between the treatment of rotator cuff tendonitis with acupuncture, dietary advice and a supplement containing bromelain, trypsin, and rutosin vs placebo supplement with assisted, active, and resisted range of motion exercise

Ethics approval required
Old ethics approval format

Ethics approval(s)
The research ethics board of the Canadian College of Naturopathic Medicine, approved on 30 October 2006

Study design
Randomized controlled parallel group study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rotator cuff tendonitis

Interventions
Supplement containing bromelain, rutin, and trypsin, and acupuncture vs placebo supplement with assisted, active, and resisted range of motion exercise

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Shoulder Pain And Disability Index (SPADI)

Key secondary outcome(s))
1. 36-item short form general health questionnaire (SF-36)
2. Shoulder range of movement
3. Orthopaedic shoulder tests

Completion date
01/08/2007

Eligibility

Key inclusion criteria
1. Males and females aged 18-65
2. Mentally competent subjects able to adhere to the given protocol and treatments administered as interventions
3. Self-selected candidates identifying themselves to suffer from pain in at least one shoulder for a period of 6 weeks or more
4. Normal on physical examination at the pre-study intake, and in the case of abnormalities the medical practitioner considers them to be clinically insignificant
5. Written and informed consent
6. The potential candidate must have a family doctor that they have seen in the last 12 months
7. A negative pregnancy test for menstruating women and a willingness to practice adequate birth control for the duration of the trial
8. Symptoms consistent with rotator cuff tendonitis, as determined by medical history or examination at screening

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
85

Key exclusion criteria
1. Mentally or physically incapacitated such that informed consent cannot be obtained
2. Any history or other condition which the study physician regards as clinically significant to the study
3. A major illness considered to be clinically significant by the study physician within 3 months of the study start date
4. Current participation in another intervention trial
5. Pregnancy or intent to become pregnant in the next 6 months
6. Medication at doses that is contraindicated with supplement (specifically daily use of warfarin, high dose aspirin, other blood thinners, or antibiotics)
7. Current alcoholism or substance abuse
8. Current history of tumors
9. Any current serious disorders determined to be clinically significant to the study
10. Breast feeding women
11. No prior shoulder surgeries, or scheduled surgeries of any kind

12. Haemophiliac, suffering from severe liver damage, or suffering from any hemorrhagic disease
13. Major shoulder joint pathology on assessment including full tendon rupture or degenerative joint disease. In these cases, referral for further evaluation and diagnosis will occur
14. Subjects with known sensitivity to any ingredient in the test product or to any member of the Bromeliaceae family, including pineapple
15. Subjects using Natural Health Products (NHPs) for 2 weeks prior to enrolment which affect shoulder pain or inflammation, contain phlogenzym or therapeutic constituents of the diet in supplement form
16. Current use of corticosteroid injection therapy

Date of first enrolment
01/02/2007

Date of final enrolment
01/08/2007

Locations

Countries of recruitment
Canada

Study participating centre
353 Thrace Ave
Ontario
Canada
L5B 2B2

Sponsor information

Organisation
The Canadian College of Naturopathic Medicine (Canada)

ROR
https://ror.org/03pjwtr87

Funder(s)

Funder type
Other

Funder Name
Canada Post, The Canadian College of Naturopathic Medicine (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/08/2009	26/03/2021	Yes	No