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A Clinical Trial Comparing Five Over-The-Counter Non-pharmacological Topical Analgesics for Myofascial Pain: single session findings

Submission date
24/10/2010

Recruitment status
No longer recruiting

Registration date
09/11/2010

Overall study status
Completed

Last Edited
04/10/2011

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

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
A Randomized, Placebo-Controlled Double-Blinded Comparative Clinical Trial of Five Over-The-Counter Non-pharmacological Topical Analgesics for Myofascial Pain: single session findings

Study objectives
This study is designed to assess the hypothesis that the five Over-The-Counter (OTC) Non-pharmacological Topical Analgesics for Myofascial Pain will perform better than the placebo cream with respect to lateral flexion range of motion and pain threshold outcome measures.

The literature on myofascial trigger points and non-pharmacologic topical agents is sparse with no randomized clinical trials found to date. A randomized, placebo-blinded clinical trial of non-pharmacological topical analgesics was conducted comparing leading national and professional brands in the treatment of a myofascial trigger point (MTP).

Please note that as of 30/11/10 this trial has not received ethics approval. Ethics approval was not obtained from the Canadian Memorial Chiropractic College Research Ethics Board in June 2009 as was stated at the time of registration. The study was performed within a private practice therapy clinic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 30/11/10: None

Study design
Single session randomised placebo controlled double blinded clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Myofascial Pain/Myofascial Trigger Points

Interventions

Six topical products were tested: three were ointments, two were roll-on gels and one placebo cream which served as the control.
1. Professional Therapy Muscle Care Roll-on (PTMC roll-on)
2. Professional Therapy Muscle Care Ointment (PTMC ointment)
3. Bengay Ultra Strength Muscle Pain ointment (BG)
4. Icy Hot Extra Strength Cream (IH)
5. Biofreeze roll-on gel (BF)
6. Non-medicinal placebo cream (PLA)
All of these products were placed in identical 0.5 ounce white plastic screw top containers or 3 ounce. generic white roll-on bottles. Only a coded letter was applied as a label. The master code for these products was kept with the clinic administrator and was unknown to all study participants.

Procedures
Subjects were seated erect in a comfortable ergonomic chair in a private room. Assessor #1 entered the room and palpated the subjects right shoulder in order to determine the presence and location of a MTP in the upper trapezius muscle adjacent to the 7th cervical vertebrae and the 1st thoracic vertebrae. This was marked with a black dot. Assessor #1 exited the room and assessor #2 entered and performed the original testing of the outcome measures. The rangiometer was placed on the subjects head. From a neutral position, right and left active end-range lateral flexion measurements were recorded. The pressure algometer was applied over the marked trapezius trigger point for the baseline pressure reading. The subject was instructed to indicate when the pressure point was painful.
Following the initial outcome measurements, assessor #1 applied one of the six samples, randomized, in the area of the marked pressure point. The subject was instructed to stay seated in the chair with little head movement for five to seven minutes. Following the application of the topical analgesic, assessor #2 reassessed and recorded the pain and range of motion outcome measures. The study was conducted over a 7-day period.

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
1. Pain at a MTP in the upper trapezius, measured using a pressure algometer and was reported in kg/cm2.
2. Cervical spine lateral flexion, measured using a cervical rangiometer and was reported in degrees.
Both measures were assessed pre- and post-intervention and have proven reliable and valid in the assessment of MTPs.

Secondary outcome measures
Patient satisfaction:
Following the intervention, subjects were asked to rate their level of satisfaction on a verbal satisfaction scale (P = poor, F = fair, G = good, E = excellent).

Overall study start date
01/07/2009

Completion date
30/07/2009

Eligibility

Key inclusion criteria
1. Male or female, aged 16-82
2. Subjects were selected from consecutive clinical presentations of patients for treatment in a multidisciplinary health clinic
3. Fifty-six percent of patients presented with shoulder or neck pain
4. Subjects were informed of the nature of the experiment and consented to participate

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120 subjects were entered into the study, 20 in each group (57:63 male:female)

Key exclusion criteria
1. Acute pain presentation preventing comfortable participation
2. Absence of a palpable tender spot in the right upper trapezius region

Date of first enrolment
01/07/2009

Date of final enrolment
30/07/2009

Locations

Countries of recruitment
Canada

Study participating centre
204 Parkmount
Toronto
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Sponsor information

Organisation
Individual Sponsor (Canada)

Sponsor details
One St Clair Avenue East
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
University/education

Funder Name
None

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