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Can magnesium applied as a foam to the skin of the leg prevent night leg cramps?

Submission date
13/11/2018

Recruitment status
No longer recruiting

Registration date
29/11/2018

Overall study status
Completed

Last Edited
27/09/2021

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims:
Approximately one in three adults suffer from night leg cramps (NLC) for which there are few safe and effective treatment options. Magnesium oxide supplementation has been explored and found ineffective; however, foam containing magnesium sulfate applied to the skin of the legs has not been examined. This study aims to investigate how well magnesium sulfate foam works in reducing NLC compared with foam containing no active ingredients (dummy foam) and whether it has an effect on quality of life. The goal is to find a treatment that will reduce night leg cramps and improve quality of life.

Who can participate?
Adults aged 18-75 years who are experiencing a minimum of 3 night leg cramps a week.

What does the study involve?
Participants who are experiencing at least 3 night leg cramps a week are asked to join the study. Participants will be randomly allocated either Foam A or Foam B to use daily for 14 days. Participants will write down how many nights they cramp and their daily symptoms (for example, pain level and severity of cramps) every day for 14 days. Participants will also fill out surveys on if they feel fatigued, their social function, sleep quality, and emotional well-being before they start using the foam and at the end of the 14 days.

What are the possible benefits and risks of participating?
There are no direct benefits for participating in the study, however there could be potential benefits for those that have success with the intervention treatment. The only risk will be for those participants that may have sensitive skin. In the event the participants have a reaction to the foam (for example, the skin gets irritated), the participant does not have to complete the study.

Where is the study run from?
Arnold School of Public Health Research Center, University of South Carolina (USA).

When is the study starting and how long is it expected to run for?
January 2017 to February 2018

Who is funding the study?
Avadim Health, Inc

Who is the main contact?
Toni M. Torres-McGehee
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of low pH magnesium sulfate foam on night leg cramps: A double-blind randomized trial

Acronym
NLC Foam Study

Study objectives
We hypothesized that a topical foam with magnesium sulfate (Theraworx Relief®+Mg) would decrease night leg cramp (NLC) spasm frequency and severity and improve quality of life measures compared with a low pH topical foam (Theraworx Relief®-pH).

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of South Carolina Institutional Review Board for Human Research, 1/9/2017. (Ame1_Pro00061216 by Expedited Review)

Study design
Randomized double-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Night leg cramps

Interventions
This was a home-based intervention within a Southeastern US urban community. Prior to enrolling participants in the study, all foam bottles were packaged by the manufacturer with the same label and shipping boxes were pre-labeled with A or B and shipped to the investigators. Advertisements were placed throughout primary care physician offices, pharmacies and the local university student health center in Columbia, SC, inviting individuals suffering from NLC to participate in the trial. Participants included were male and female adults who experienced a minimum of 3 night cramps per week. The participants were randomized to group A or B using the online randomization scheme sealed envelope™ (https://www.sealedenvelope.com/simple-randomiser/v1/lists). As eligible participants enrolled in the study, they were assigned an ID

number and corresponding group. Both investigators and participants were blind to the intervention treatments. The intervention group was given 5 bottles of low pH topical foam with magnesium sulfate (Theraworx Relief®+Mg) and followed a treatment plan for 14 consecutive days. The control group was given 5 bottles of the low pH topical foam (Theraworx Relief®-pH) and followed a treatment plan for 14 consecutive days. All pre- and post- data were collected within home and lab settings at the Arnold School of Public Health from May 2017 through February 2018. After all data was collected and analyzed, the manufacturer provided formulations of each foam to the investigators to determine group assignment.

Intervention Type
Supplement

Primary outcome measure
Number of NLCs per week during the 14 consecutive days of the intervention

Secondary outcome measures
1. Social function assessed using the Restless Leg Syndrome Quality of Life Questionnaire at baseline and day 14
2. Daily function assessed using the Restless Leg Syndrome Quality of Life Questionnaire at baseline and day 14
3. Sleep quality assessed using the Restless Leg Syndrome Quality of Life Questionnaire at baseline and day 14
4. Emotional well-being were assessed by using the Restless Leg Syndrome Quality of Life Questionnaire at baseline and day 14
5. Daytime fatigue assessed using the Multi-Dimensional Fatigue Inventory at baseline and day 14

Overall study start date
05/01/2017

Completion date
15/02/2019

Eligibility

Key inclusion criteria
1. Aged 18-75 years
2. Experiencing a minimum of 3 NLCs a week

Participant type(s)
Mixed

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
50 was the target, however we were only able to recruit 36 to complete the entire study. We had a total of 57 inquiries, with 18 being excluded due to not meeting the criteria, and 7 did not return recruitment calls. We had 39 start the study, with 3 dropping out for non-compliance of the study or they didn't see immediate results.

Total final enrolment
36

Key exclusion criteria
1. Patients nearing death
2. Taking medications causing NLCs
3. Adverse response to any topical foams
4. Allergy to magnesium or sulfur
5. Skin cuts
6. Active tissue or bone infections
7. Current foot or leg fractures

Date of first enrolment
01/04/2017

Date of final enrolment
15/02/2018

Locations

Countries of recruitment
United States of America

Study participating centre
Public Health Research Center
921 Assembly Street
Columbia
United States of America
29201

Sponsor information

Organisation
University of South Carolina - Institutional Review Board

Sponsor details

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Sponsor type
Industry

Website
https://sc.edu/about/offices_and_divisions/research_compliance/irb/index.php

ROR
https://ror.org/02b6qw903

Funder(s)

Funder type
Industry

Funder Name
Avadim Health Inc

Results and Publications

Publication and dissemination plan
We currently have already collected data and would like to register the trial and the submit for publication to JAMA Internal Medicine as soon as we get registered. Submission is pending registration of the trial.

Intention to publish date
01/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Toni Torres-McGehee (torresmc@mailbox.sc.edu). The study protocol, statistical analysis plan, and individual participant data that underlie the results reported in this article, after deidentification (text, figures, and tables) can be shared. Data will be available beginning 3 months and ending 5 years following article publication. Data will be available for researchers who provide a methodically sound proposal to achieve aims in the approved proposal. Proposals should be directed to torresmc@mailbox.sc.edu. To gain access, applicants will need to sign a data access agreement.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/06/2019	27/09/2021	No	No