

Are regular calf-stretching exercises effective in the management of nocturnal leg cramps? A controlled trial

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/01/2010	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

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

SPGS787

Study information

Scientific Title

Acronym

MONC

Study objectives

Are regular calf-stretching exercises effective in the management of nocturnal leg cramps? Nocturnal leg cramps are painful muscle spasms which commonly disrupt sleep. Their cause is unclear and they are frequently treated with quinine which is potentially toxic and costly to the NHS. In 1979 a small, uncontrolled trial suggested that a simple programme of leg muscle stretching exercises could prevent nocturnal leg cramps. This has been widely cited but no attempt seems to have been made to confirm or refute its conclusions. We intend to establish whether such exercises are effective, feasible and whether they reduce quinine use. To determine whether regular exercises are effective and feasible in the treatment of leg cramps.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Other symptoms and general pathology

Interventions

1. Stretching exercises
2. Non-stretching exercises and continuation of quinine treatment

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Diary of incidence
2. Frequency
3. Duration and severity of leg cramps
4. Subsequent GP attendance
5. Quinine and analgesic prescriptions

Secondary outcome measures

Not provided at time of registration

Overall study start date

31/12/1998

Completion date

31/12/2002

Eligibility**Key inclusion criteria**

191 patients from general practices aged 60 and over being prescribed quinine

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

191

Key exclusion criteria

1. Previously taught cramp-preventing exercises
2. Unable to undertake exercises
3. Other conditions causing leg pain
4. Unable to report symptoms reliably

Date of first enrolment

31/12/1998

Date of final enrolment

31/12/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Research Office

Basingstoke

United Kingdom

RG25 3DZ

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

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SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2005		Yes	No