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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 12/01/2010	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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
United Kingdom

England

Study participating centre
Research Office
Basingstoke
United Kingdom
RG25 3DZ

Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
NHS Executive South East (UK)

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	results	01/03/2005		Yes	No