ISRCTN42466047 https://doi.org/10.1186/ISRCTN42466047

The effect of using copper heelers in alleviating joint and musculoskeletal aches and pains

Submission date
05/03/2010

Recruitment status
No longer recruiting

Registration date
18/03/2010

Overall study status
Completed

Last Edited
01/11/2019

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

Protocol serial number
Version 4 - 23rd February 2010

Study information

Scientific Title

The effect of using copper heelers in alleviating joint and musculoskeletal aches and pains: A double blinded, randomised, placebo controlled trial

Acronym
CH

Study objectives
Investigation of the effect of copper heelers (insoles) in a controlled randomised double blind trial in relieving joint and musculoskeletal aches and pains.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. South Staffordshire research ethics committee, 04/03/2010
2. Royal Wolverhampton hospital trust research and development, 18/01/2010

Primary study design
Interventional

Study design
Randomised double-blind placebo-controlled parallel-group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rheumatology

Interventions
Randomisation between the copper heeler and placebo heeler will be carried out by the research nurse, by use of a concealed envelope system which will be co-ordinated and recorded by the chief investigator. Patients will be provided with written instructions and training on how to use, care for and dispose of the device. Patients will be required to attend the rheumatology clinic on 6 occasions. Actual usage of the device will be for a period of 12 weeks to collect the study data. Initial assessment will include demographic data, diagnosis, arthritic symptoms and painful sites affected. Details of medication, in particular painkillers, anti-inflammatories and exact dose of these will also be recorded. A baseline visual analogue scale will be used to benchmark their current status along with a simple patient questionnaire to ask patients whether they have had any changes in their symptoms and daily activities, and the device's general usability. Following assessments will consist of a visual analogue scale to assess any change in arthritic symptoms. The frequency and the dose of painkillers and/or the anti-inflammatories will be recorded. At various timepoints another patient questionnaire will be completed to assess any change in symptoms, daily activities and usage.
The total duration of the intervention is 12 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Beneficial effects will be judged by a minimum of 20% or more improvement in arthritic symptoms and/or 20% or more in reduction of frequency and dose of painkillers and/or anti-inflammatory medication, as judged by visual analogue scale (VAS) score
2. Reduction of pain and stiffness in a joint, as judged by
2.1. Activity score (e.g., comfort of walking)
2.2. Hospital anxiety depression scale (HADS)
2.3. Health assessment questionnaire (HAQ) scores
Outcomes will be assessed at baseline and completion of 100 and 200 participants.

Key secondary outcome(s)
1. Time taken from 1st usage of the device to it giving some relief of symptoms
2. Dosage of medications taken from 1st use of the device to last study visit
3. Frequency of medications taken from 1st use of the device to last study visit
4. Change in day-to-day activities
Outcomes will be assessed at baseline and completion of 100 and 200 participants.

Completion date
04/03/2010

Eligibility

Key inclusion criteria
1. Adult males and females, age 16 to 80 years
2. On stable medication (painkillers and anti-inflammatories) without any change for a period of 4 weeks pre-entry (no new drugs have been introduced within that time period and there has been no significant change in pattern of analgesia usage within the current drug regime)
3. Joint and musculoskeletal aches and pains can be present in any part of the body, not just lower limbs
4. Attendees of a rheumatology clinic with confirmed clinical diagnosis of arthritis, inflammatory arthritis i.e. rheumatoid arthritis provided that no steroids in the form of joint injections, oral steroids or intra muscular (IM) depomedrone have been used for three months pre-trial and are unlikely to be required for the period of the trial
5. On stable disease modifying anti-rheumatic drugs without any change or addition for three months pre-trial
6. Osteoarthritis
7. Mental ability to follow instructions as judged by investigator
8. Good understanding of oral and written English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. No known allergy or otherwise intolerance to copper
2. Not pregnant or undergoing pre-conception planning interventions
3. Inability to provide written informed consent
4. Age <16 or >80 years
5. Received steroids in the form of joint injections, oral steroids or IM depomedrone within three months pre-trial
6. Likely to require steroids in the form of joint injections, oral steroids or IM depomedrone during the trial

Date of first enrolment
04/03/2010

Date of final enrolment
04/03/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Wolverhampton
Wolverhampton
United Kingdom
WV1 1DT

Sponsor information

Organisation
University of Wolverhampton Corporate Services Ltd (UK)

ROR
https://ror.org/01k2y1055

Funder(s)

Funder type
Industry

Funder Name
Anthony Andrews Master Shoemaker (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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes