ISRCTN13668166 https://doi.org/10.1186/ISRCTN13668166

A double-blind multi-centre randomised controlled trial to investigate the effectiveness of methylprednisolone injections in the treatment of Morton's neuroma

Submission date
03/10/2008

Recruitment status
No longer recruiting

Registration date
12/11/2008

Overall study status
Completed

Last Edited
05/03/2015

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Colin Thompson

Contact details
School of Health Sciences
Queen Margaret University
Edinburgh
United Kingdom
EH21 6UU
-
cthomson@qmu.ac.uk

Additional identifiers

Protocol serial number
2001/RUO/04

Study information

Scientific Title
A double-blind multi-centre randomised controlled trial to investigate the effectiveness of methylprednisolone injections in the treatment of Morton's neuroma

Acronym
MoRTISE

Study objectives
The trial is designed primarily to address the question: is local injection of steroid (methylprednisolone) an effective treatment for Morton's neuroma? Thus we seek to test the following null hypothesis: that steroid injections are as effective as anaesthetic injections for the pain and the effects of pain associated with Morton's neuroma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lothian Research Ethics Committee (Orthopaedic surgery/surgery Research ethics sub-committee), 23/11/2000, ref: LREC/2000/5/31

Study design
Incremental cost-effectiveness analysis and single-blind pragmatic randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Morton's neuroma

Interventions
Participants will be allocated to receive steroid and anaesthetic (injection of 1 ml methylprednisolone and 1 ml 2% lignocaine) or just anaesthetic (2 ml of 1% lignocaine). All ultrasound examinations and injections will be performed by the same musculoskeletal radiologist using an ATL HDI 5000 (Seattle, Washington) with a 7-12MHz transducer. Neuroma will be injected by a plantar approach. Patients will receive only a single injection and patints will be reviewed clinically after 3 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Methylprednisolone

Primary outcome(s)

1. Patient completed booklet of outcome measures, comprehensive yet brief, will cover the following domains:
1.1. Foot Health Status - the Foot Thermometer, a validated 10 cm visual analogue scale of foot health, will be the primary outcome measure. A validated questionnaire-based measure of foot health status will complement it.
1.2. Functional Disability - the Manchester Foot Pain and Disability Schedule has been validated for use as a measure of disability specifically associated with foot pain
1.3. Pain - the Multidimensional Affect and Pain Survey (MAPS) is a widely validated questionnaire developed from cluster analysis of common descriptors for pain and its effects. It covers three dimensions: pain as a sensory experience; suffering associated with pain; and uniquely, for this type of measurement tool, general well-being in the presence of pain.
1.4. General Health Status - the EuroQol, a single validated index for describing and valuing health states. It consists of five items - mobility, self-care, usual activities, pain or discomfort, and anxiety or depression - and a visual analogue scale of global health status.
2. Need for surgical excision of the digital nerve, based on explicit criteria
3. The size of the neuroma, as determined by ultrasonic scan

All measured at 1 month, 3 months and 12 months.

Key secondary outcome(s))
Patients will receive essentially the same outcome booklets as above 1, 3 and 12 months after treatment. In the case of non-response to postal questionnaires, the research secretary will send out written reminders to patients after 1 and 2 weeks: the research secretary will also contact patients by telephone at the time of posting the second reminder. Additional clinical information, such as adverse events, will be documented by the trial clinical co-ordinator at the clinical review appointment after four months. This information will be forwarded, by post, directly to the research secretary as part of the usual routine of clinical documentation.

Completion date
31/07/2005

Eligibility

Key inclusion criteria
All patients (adult, either sex) referred to outpatient clinics at The Royal Infirmary Edinburgh (RIE), St John's Hospital Livingston and Queen Margaret University College (QMUC) with a diagnosis of Morton's neuroma, confirmed by a diagnostic ultrasound scan, will be considered for inclusion in the trial.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Contraindications to methylprednisolone or lignocaine such as pregnancy, breast-feeding or peripheral vascular disease
2. Communication difficulties as judged by the recruiting clinician
3. Received a recent injection of steroid for Morton's neuroma

Date of first enrolment
01/08/2003

Date of final enrolment
31/07/2005

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Queen Margaret University
Edinburgh
United Kingdom
EH21 6UU

Sponsor information

Organisation
Queen Margaret University (UK)

ROR
https://ror.org/002g3cb31

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office of the Scottish Executive Health Department (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	01/05/2013		Yes	No
Results article	economic evaluation results	25/02/2015		Yes	No