

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

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<b>Registration date</b> 12/11/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/03/2015	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

-  
cthompson@qmu.ac.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 patients will be reviewed clinically after 3 months.

## **Intervention Type**

Drug

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Methylprednisolone

## **Primary outcome measure**

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.

## **Secondary outcome measures**

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.

## **Overall study start date**

01/08/2003

## **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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

150 patients (75 in each group)

**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**

Scotland

United Kingdom

**Study participating centre**

Queen Margaret University

Edinburgh

United Kingdom

EH21 6UU

**Sponsor information****Organisation**

Queen Margaret University (UK)

### **Sponsor details**

Queen Margaret University Drive  
Edinburgh  
Scotland  
United Kingdom  
EH21 6UU

-  
jtait@qmu.ac.uk

### **Sponsor type**

University/education

### **Website**

<http://www.qmu.ac.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**

### **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?
<a href="#">Results article</a>	results	01/05/2013		Yes	No
	economic evaluation results				

