

Effect of methotrexate in post-operative wound healing in rheumatoid patients undergoing foot and ankle surgery

Submission date 30/09/2005	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/04/2011	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Nick Emms

Contact details

Department of Orthopaedics
Wirral Hospital NHS Trust
Arrowe Park Road
Upton
Wirral
United Kingdom
CH49 5PE
+44 (0)151 678 5111
nick.emms@ukonline.co.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0280141217

Study information

Scientific Title

Study objectives

Does methotrexate affect post-operative wound healing in rheumatoid patients undergoing foot and ankle surgery?

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)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Surgery: Foot and ankle

Interventions

Group A: continuous methotrexate therapy for two weeks during perioperative period

Group B: omit methotrexate therapy for two weeks during perioperative period

Added September 2008: trial stopped due to poor recruitment.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

methotrexate

Primary outcome measure

1. Rate of wound infection
2. Patient pain levels

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/05/2004

Completion date

01/05/2005

Reason abandoned (if study stopped)

Poor recruitment

Eligibility

Key inclusion criteria

Rheumatoid patients on methotrexate therapy undergoing foot and ankle surgery.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Sample of 200 patients in each group.

Key exclusion criteria

1. Ongoing use of other immunosuppression agents.
2. Localised infection pre-operatively.

Date of first enrolment

01/05/2004

Date of final enrolment

01/05/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Orthopaedics
Wirral
United Kingdom
CH49 5PE

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type
Government

Funder Name
Wirral Hospitals NHS Trust (UK), NHS R&D Support Funding

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