

A prospective, single-centre, randomised, double-blind, placebo-controlled trial to assess the analgesic effects of one-week treatment with anti-tumour necrotising factor (TNF) in patients with lower back and leg pain

Submission date 29/09/2006	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 29/09/2006	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 07/10/2014	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N0205172997

Study information

Scientific Title

Study objectives

To establish if there is any acute analgesic effect of anti-tumour necrotising factor (TNF) treatment in patients with lower back and leg pain.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Prospective single-centre randomised double-blind placebo-controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lower back and leg pain

Interventions

Patients are randomised to:

1. One week treatment with anti-tumour necrotising factor (TNF)
2. One week treatment with placebo

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Anti-TNF

Primary outcome(s)

Severity of pain as identified by Visual Analogue Scale (VAS).

Key secondary outcome(s)

Not provided at time of registration

Completion date

10/05/2007

Eligibility

Key inclusion criteria

1. Patients must be willing and able to give written informed consent prior to admission to the study
2. Patients must be American Society of Anesthesiologists (ASA) grade I - III
3. Patients must be aged 18 - 65 years
4. Patients must be scheduled to undergo epidural steroid injection (ESI) for lower back pain of more than one month's duration and up to nine months
5. Patients must have had a chest X-ray prior to admission to the study, within the last six months
6. Females of the childbearing age must have a negative urine pregnancy test on the day of the study, and be using an acceptable method of contraception

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. A history of diabetes mellitus
2. A history of uncontrolled chronic disease
3. Evidence of immunosuppression (including current steroid treatment), immunodeficiency or human immunodeficiency virus (HIV) positive status
4. History of tuberculosis (TB)
5. Pain for less than one month or more than nine months duration
6. Previous back surgery
7. Previous chronic pain interventions
8. Presence of any of the following:
 - 8.1. Recent bowel or bladder disturbance
 - 8.2. Motor deficit
 - 8.3. Saddle anaesthesia
 - 8.4. Suspected malignancy (primary or secondary)
9. Any other back pain 'red flag' symptoms and signs, identified by the patient's clinicians or the study investigators
10. A history of spinal or neurological disease
11. A history of congestive cardiac failure
12. Known hypersensitivity to anti-TNF
13. A history of previous administration of anti-TNF

14. Any contraindications to anti-TNF in the Summary of Product Characteristics

15. Pregnancy or lactation

16. Patients who are unwilling or unable to conform to the protocol

Date of first enrolment

11/11/2005

Date of final enrolment

10/05/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Pain Research Group

London

United Kingdom

EC1A 7BE

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Barts and The London NHS Trust (UK)

Funder Name

Queen Mary University of London (QMUL) (UK)

Alternative Name(s)

QMUL

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Funder Name

NHS R&D Support Funding (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration