ISRCTN14943354 https://doi.org/10.1186/ISRCTN14943354

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

Registration date
29/09/2006

Last Edited
07/10/2014

Recruitment status
No longer recruiting

Overall study status
Completed

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
11/11/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. A history of diabetes mellitus
2. A history of uncontrolled chronic disease
3. Evidence of immunosupression (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
England

United Kingdom

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)

Sponsor details
The Department of Health
Richmond House
79 Whitehall

London
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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
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

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