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Efficacy and cost-effectiveness analysis of oral diclofenac sodium 3 days, 7 days for conventional radiofrequency denervation in the treatment of chronic facet joint pain: double-blinded randomised controlled trial

Submission date
23/08/2008

Registration date
12/09/2008

Last Edited
09/05/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Signs and Symptoms

[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
1. Diclofenac sodium can decrease the pain degree, and improve the patient's satisfaction after conventional radiofrequency denervation
2. Compared to 7 days dosage, 3 days diclofenac sodium therapeusis has the same efficacy and better cost-effectiveness for the treatment of pain after conventional radiofrequency denervation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Shanghai Sixth People's Hospital, Shanghai Jiaotong University. Date of approval: 20/08/2008

Study design
Prospective, double-blinded, randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic low back facet joints pain

Interventions
Arm 1: Placebo 3 times daily (tid) for 7 days
Arm 2: Diclofenac sodium 25 mg tid for 3 days and placebo tid for following 4 days
Arm 3: Diclofenac sodium 25 mg tid for 7 days

Total duration of treatment: 7 days
Total duration of follow-up: 60 days

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Diclofenac sodium

Primary outcome measure
1. Pain, measured by a visual analogue scale (VAS) at baseline, Day 7, 14, 30, 60
2. Oswestry Disability Index (ODI) at baseline, Day 30 and 60
3. Cost-effectiveness analysis at 60 days

Secondary outcome measures
1. Overall patients' satisfaction, measured by Patients' Satisfaction Score (3: excellent; 2: good; 1: moderate; 0: bad) at Day 60
2. Number needed to treat (NNT) to obtain one patient with good or complete pain relief at Day 60
3. Dosage of rescue drug. Duration of follow-up: 60 days after radiofrequency denervation.
4. Presence, frequency and duration of adverse effects at Day 7, 14, 30, 60

Overall study start date
03/09/2008

Completion date
30/03/2009

Eligibility

Key inclusion criteria
1. Both males and females, age greater than 18 years
2. Duration of facet joints pain more than 6 months
3. Oswestry disability index 20%+
4. Unresponsiveness to traditional conservative treatments such as bed rest, medication, physical therapy, trigger point injection and epidural block

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
66

Key exclusion criteria
1. Prior radiofrequency treatment
2. Coagulation disturbances
3. Allergies to local anaesthetic
4. Malignancy
5. Mental handicap or psychiatric condition precluding adequate communication, language problems
7. Unstable medical or psychiatric condition
8. Pregnancy
9. No effect of diagnostic blockades (one or two)
10. Gastrointestinal tract ulcer
11. Radicular syndrome
12. Indication for low back surgery

Date of first enrolment
03/09/2008

Date of final enrolment
30/03/2009

Locations

Countries of recruitment
China

Study participating centre
Department of Anaesthesiology and Pain Centre
Shanghai
China
200233

Sponsor information

Organisation
Shanghai Sixth People's Hospital (China)

Sponsor details
Department of Anaesthesiology and Pain Centre
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/049zrh188

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Shanghai Sixth People's Hospital Clinical Research Fund (China)

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?
Results article	results	01/01/2011		Yes	No