

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	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/05/2011	Condition category Signs and Symptoms	☐ 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

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

Primary study design

Interventional

Study design

Prospective, double-blinded, randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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

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?
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[Results article](#)

results

01/01/2011

Yes

No