# 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	<ul><li>Prospectively registered</li></ul>		
		Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/09/2008	Completed	[X] Results		
<b>Last Edited</b> 09/05/2011	<b>Condition category</b> Signs and Symptoms	[] Individual participant data		

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

### Contact name

Dr Ma Ke

### Contact details

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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

# 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 Shanghai Sixth People's Hospital Shanghai JiaoTong University 600 Yi-Shan Road Shanghai China 200233

# 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