

A clinical trial of Diosmin's effects in the treatment of low back pain

Submission date 09/06/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/06/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/07/2018	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims:

Radicular pain is a type of pain that is caused by compression of a nerve in the spine. The pain is often felt in the area of the body that is supplied by that nerve, such as leg pain caused by compression of a nerve supplying the leg. Around 10-15% of patients with radicular pain undergo surgery to correct the problem eventually, however most use pain relieving drugs to control the pain levels. Diosmin is a type of plant chemical found mainly in citrus fruits, which is used for treating various conditions. It is thought to work by reducing inflammation (swelling). The aim of this study is to find out whether treatment with Diosmin may be effective in the treatment of radicular pain.

Who can participate?

Adults who have been diagnosed with radicular pain

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are treated with Diosmin for one month. Those in the second group are treated with a commonly used pain relieving treatment for one month. Participants in both groups are asked to rate their pain levels and satisfaction with treatment when they first receive their treatment and again after two and eight weeks.

What are the possible benefits and risks of participating?

Participants who receive the Diosmin may benefit from a reduction in pain and greater levels of satisfaction. There are no notable risks involved with participating.

Where is the study run from?

Nanjing Drum Tower Hospital (China)

When is study starting and how long is it expected to run for?

March 2008 to December 2011

Who is funding the study?

National Natural Science Foundation of China (China)

Who is the main contact?
Professor Yinhe Wang

Contact information

Type(s)
Scientific

Contact name
Prof Yinhe Wang

ORCID ID
<http://orcid.org/0000-0003-2354-5049>

Contact details
Department of Orthopedic Surgery
Nanjing Drum Tower Hospital
Nanjing University Medical School
321 Zhongshan Road
Jiangsu
Nanjing
China
210008

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DTH-2017010

Study information

Scientific Title
A randomized controlled trial evaluating the effects of Diosmin in the treatment of radicular pain caused by lumbar intervertebral disc protrusion

Study objectives
Diosmin at a dose of 50 mg/kg/day may reduce the radicular pain from lumbar intervertebral disc protrusion and has no effect difference with currently used active treatment of mannitol plus dexamethasone.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics Committees of Drum Tower Hospital of Nanjing University Medical School, 30/08/2008, ref: DTH-2017010

Study design

Non-Inferiority randomised active-controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Radicular pain

Interventions

Participants are randomised to one of two groups using a single randomisation technique.

Intervention group: Participants receive Diosmin (Nanjing Chia Tai Tianqing Pharmaceutical Co., Ltd) per os, 900 mg, tid for 2 weeks followed by bid for 2 weeks, and lastly 450 mg bid as maintenance dose for at least one month.

Control group: Participants receive 20% mannitol (CR Double-Crane Pharmaceuticals Co., Ltd) 250ml (1g/kg/day) and dexamethasone (Furuitang Pharmaceutical Co., Ltd) 10 mg/day intravenous drops for the first 3 days and followed by mannitol for 4 days.

In the both groups, the course of treatment lasts for at least one month.

Participants in both groups rate their pain levels and satisfaction with treatment at initial drug administration and after two and eight weeks.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Diosmin

Primary outcome measure

1. Perceived pain is measured using a visual analogue scale (VAS) and a numerical rating scale (NRS) just after the administration of drugs, and two and eight weeks later
2. Self-rated physical disability is measured using the Roland-Morris questionnaire (RM-Q) just after the administration of drugs, and two and eight weeks later

Secondary outcome measures

Patient's satisfaction is measured using a three-grade scale ranging from completely satisfied (no pain at all time and no restriction of activities) to satisfied (slight pain that requires no medication and mild restriction of activities) to unsatisfied (moderate to severe pain that requires medication and moderate to severe restriction of activities) via telephone after two years.

Overall study start date

01/03/2008

Completion date

01/12/2011

Eligibility

Key inclusion criteria

1. Preliminary diagnosis of radicular pain
2. Aged 18 years and over
3. Pain duration at least 30 days
4. Underwent routine discography
5. Previously treated with nonsteroidal anti-inflammatory drugs, opioid medications or physical therapy without pain relief for more than one month
6. Normal or slight decrease in the height of disc space on lateral plain X-ray film
7. Initially considered eligible for surgical intervention

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

300

Key exclusion criteria

1. Spondylolysis
2. Lumbar canal stenosis
3. Isthmic or degenerative spondylolisthesis
4. Inflammatory arthritis

5. Spinal instability
6. Infection from previous lumbar surgery
7. Neurologic disease
8. Tumor
9. Psychological disorders (such as depression or using antidepressant/anxiolytic medications)

Date of first enrolment

01/01/2009

Date of final enrolment

30/06/2009

Locations

Countries of recruitment

China

Study participating centre**Nanjing Drum Tower Hospital**

Nanjing University Medical School

321 Zhongshan Road

Jiangsu

Nanjing

China

210008

Sponsor information

Organisation

Nanjing Drum Tower Hospital

Sponsor details

Nanjing University Medical School

321 Zhongshan Road

Jiangsu

Nanjing

China

210008

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/026axqv54>

Funder(s)

Funder type

Government

Funder Name

National Natural Science Foundation of China

Alternative Name(s)

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, NSFC, NNSF, NNSFC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

China

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal in 2017.

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not publicly available due to the privacy of these data, but are available from the corresponding author upon reasonable request.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2017		Yes	No
Basic results		13/06/2017	28/06/2017	No	No