ISRCTN97157037 https://doi.org/10.1186/ISRCTN97157037

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

Submission date 09/06/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/06/2017	**Overall study status** Completed	
Last Edited 10/07/2018	**Condition category** Signs and Symptoms	

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
https://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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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.

Completion date
01/12/2011

Eligibility

Key inclusion criteria
1. Preliminarily 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

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 Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes