Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the clinical outcomes of percutaneous vertebroplasty vs. kyphoplasty for the treatment of osteoporotic Kümmell’s disease

Protocol summary

Study aim
The purpose of this article is to investigate the clinical efficacy of PVP and PKP for Kümmell's disease.

Design
This study is a prospective, randomized, controlled study. The patients were blinded, but the researchers were not fully blinded.

Settings and conduct
The patients were blinded. Researchers were not fully blinded.

Participants/Inclusion and exclusion criteria
The inclusion criteria : ① single-segment Kümmell's disease without new OVCF in the adjacent vertebrae; ② Computed tomography (CT) or magnetic resonance imaging (MRI) examination confirmed the existence of IVC. ④ Dual energy X-ray measurement of bone mineral density (BMD) T value was less than -2.5; ⑤ PVP or PKP was conducted with bilateral pedicle; ⑥ Follow-up time was more than 2 years; ⑦ Postoperative calcium supplementation and anti-osteoporotic drugs were applied; ⑧ No fall or other trauma occurred. Exclusion criteria : ① Patients with severe cardiopulmonary dysfunction; ② Patients with coagulopathy; ③ Patients with local or systemic infection; ④ Patients with nerve root or spinal cord compression symptoms; ⑤ Patients with pathological fractures other than osteoporosis.

Intervention groups
56 of the 64 patients with Kümmell’s disease met the selection criteria for inclusion in the study, of which 28 cases received percutaneous vertebroplasty treatment (PVP group) and 28 cases received percutaneous kyphoplasty (PKP group) . Both groups of surgeries were performed by the same group of physicians.

Main outcome variables
1.Visual analogue scale (VAS); 2.Oswestry disability index (ODI) ; 3.The bone cement leakage rate; 4.Bone cement injection amount; 5.Operation time; 7.the rate of vertebral compression; 8.Correction rate of kyphosis; 9.Refracture rate of adjacent vertebra.

General information

Reason for update

Acronym
Percutaneous Vertebroplasty Trial

IRCT registration information
IRCT registration number: **IRCT20200325046855N1**
Registration date: **2020-04-11, 1399/01/23**
Registration timing: **prospective**

Last update: **2020-04-11, 1399/01/23**
Update count: **0**

Registration date
2020-04-11, 1399/01/23

Registrant information

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CR & WISCO General Hospital

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Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2637-02-20, 2015/12/01

Expected recruitment end date
2639-02-20, 2017/12/01

Actual recruitment start date
2637-02-24, 2015/12/05

Actual recruitment end date
2639-03-22, 2018/01/02

Trial completion date
2641-03-22, 2020/01/02

Scientific title
Comparison of the clinical outcomes of percutaneous vertebroplasty vs. kyphoplasty for the treatment of osteoporotic Kümmell’s disease

Public title
Effect of percutaneous vertebroplasty vs. kyphoplasty in treatment of Kümmell’s disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients suffered single-segment Kümmell's disease without new OVCF in the adjacent vertebrae; Computed tomography (CT) or magnetic resonance imaging (MRI) examination confirmed the existence of IVC. the IVC refers to a significant radiolucency (gas containing), which is located centrally or adjacent to the vertebral body endplates as seen on CT or plain radiographs. On MRI, it is usually shown as a low signal intensity on a T1-weighted image and as a high signal or a low signal on a T2-weighted image, depending on whether the fluid or gas fills the cleft; Dual energy X-ray measurement of bone mineral density (BMD) T value was less than -2.5; PVP or PKP was conducted with bilateral pedicle; Follow-up time was more than 2 years Postoperative calcium supplementation and anti-osteoporotic drugs were applied; No fall or other trauma occurred.

Exclusion criteria:
Patients with severe cardiopulmonary dysfunction; Patients with coagulopathy; Patients with local or systemic infection; Patients with nerve root or spinal cord compression symptoms; Patients with pathological fractures other than osteoporosis.

Age
From **55 years** old to **90 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Actual sample size reached: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
Method of randomization Simple randomization. Unit of randomization : individual. Tools used in randomization : table of random numbers. We set up a random sequence from a random number table. No undistributed concealment was made.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients were blinded. The patient only knew that the operation was vertebroplasty, but did not know that it was PVP or PKP surgery. Therefore, patients did not know the specific grouping. Patients, principle investigator, healthcare providers, data safety and monitoring board and nurses didn't know exactly what kind of intervention was done. Physicians, investigators, data collectors,and outcome assessor knew about the subgroups.

Placebo
Not used

Assignment
Parallel

Other design features
no

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committees of CR & WISCO General Hospital

Street address
209

City
Wuhan

Postal code
430080

Approval date
2637-01-15, 2015/10/25

Ethics committee reference number
hrwg20151025

Health conditions studied

1

Description of health condition studied
Kümmell’s disease is a special type of osteoporotic vertebral compression fracture (OVCF), which is relatively rare in clinical practice. Kümmell's disease is also known as nonunion after OVCF, delayed vertebral osteonecrosis after trauma, and delayed vertebral collapse. Imaging examination can discover the late-onset collapse of vertebrae and characteristic change of intravertebral vacuum cleft (IVC), which is considered one of important inducing factors for injured vertebral progress after the collapse, deformity of kyphosis, intractable back pain and spinal cord damage after OVCF.

ICD-10 code
D49.2

ICD-10 code description
Neoplasm of unspecified behavior of bone, soft tissue, and skin

Primary outcomes

1

Description
the Oswestry disability index (ODI)

Timepoint

before surgery, at 1 days, 1 year and 2 years after surgery

Method of measurement

The ODI scale was used to evaluate the severity of the dysfunction [9].

2

Description

visual analogue scale (VAS)

Timepoint

before surgery, at 1 days, 1 year and 2 years after surgery

Method of measurement

VAS is measured according to visual analogue scale

3

Description

Bone cement leakage rate

Timepoint

After surgery

Method of measurement

X-ray film is used to observe whether there is leakage of bone cement.

4

Description

The incidence of new adjacent vertebral fracture

Timepoint

at 1 days, 1 year and 2 years after surgery

Method of measurement

X-ray film is used to observe whether there is a new adjacent vertebral fracture.

5

Description

Rate of vertebral compression

Timepoint

before surgery, at 1 days, 1 year and 2 years after surgery

Method of measurement

Imaging measurement indexes: the height of the injured vertebral body and the kyphosis angle were measured before and after the operation by the anteroposterior and lateral X-ray images[10]. And the following indexes were calculated. 1) Rate of vertebral compression = the height of the injured vertebral body / the average height of adjacent upper and lower vertebral body heights [10];

6

Description

Correction degree of kyphosis

Timepoint

before surgery, at 1 days, 1 year and 2 years after surgery

Method of measurement

Imaging measurement indexes: the height of the injured vertebral body and the kyphosis angle were measured before and after the operation by the anteroposterior and lateral X-ray images[10]. And the following indexes were calculated. Correction degree of kyphosis = (preoperative kyphosis angle - postoperative kyphosis angle) / preoperative kyphosis angle × % [11].

Secondary outcomes

1

Description

Complications of bone cement

Timepoint

intraoperation and postoperation

Method of measurement

Closely observe the patient's symptoms and consult chief complaint and conduct related clinical examination

Intervention groups

1

Description

Intervention group: PVP group of surgeries were performed by the same group of physicians, and the PVP procedures followed the same principle. The patients were placed in the prone position to maintain the spine's posterior extension for position reduction. Bilateral pedicle puncture with local anesthesia guided by C-arm X-ray machine. The working sleeve reached the IVC area in the anterior 1/3 of the vertebra or close to the IVC area. Polymethylmethacrylate (Tecres SPA, Verona, Italy) was injected into the IVC region using a 3.5mm side opening bone cement injector (Shanghai Kinetic Medical Co., Ltd., Shanghai, China) until the entire crack was fully filled and the cement was well dispersed. Finally, the bone cement was injected into the IVC region through the side opening injector until the entire fracture was filled.

Category

Treatment - Surgery

2

Description

Control group: PKP group of surgeries were performed by the same group of physicians, and the PKP procedures followed the same principle. The patients were placed in the prone position to maintain the spine's posterior extension for position reduction. Bilateral pedicle puncture with local anesthesia guided by C-arm X-ray machine. The working sleeve reached the IVC area in the anterior 1/3 of the vertebra or close to the IVC area. Polymethylmethacrylate (Tecres SPA, Verona, Italy) was injected into the IVC region using a 3.5mm side opening bone cement injector (Shanghai Kinetic Medical Co., Ltd., Shanghai, China) until the entire crack was fully filled and the cement was well dispersed. After the working sleeve reached the IVC area, the extended balloon catheter (Shanghai Kinetic Medical Co., Ltd., Shanghai, China) was first delivered to the IVC area through the work channel. The balloon was expanded, and the pressure of the balloon system was controlled within 15

atmospheres to make the satisfactory reduction of the fractures around the IVC area and the corresponding endplate. Finally, the bone cement was injected into the IVC region through the side opening injector until the entire fracture was filled.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

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Grant name
the National Natural Science Foundation of China
Grant code / Reference number
31671235
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Natural Science Foundation of China
Proportion provided by this source
50
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Comparison of the clinical outcomes of percutaneous vertebroplasty vs. kyphoplasty for the treatment of osteoporotic Kümmell’s disease
When the data will become available and for how long
starting 6 months after publication.
To whom data/document is available
only available for people working in academic institutions or people working in businesses can also apply to receive it.
Under which criteria data/document could be used
Information about who will review requests and criteria for reviewing requests may also be provided.
From where data/document is obtainable
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.
What processes are involved for a request to access data/document
send information of these documents /data files via email or share it on a website.
Comments
no