

Pain and function of patients with knee osteoarthritis were improved after receiving therapeutic exercise plus intraarticular medicine injection

Submission date 25/07/2017	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 31/07/2017	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 23/01/2019	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Knee OA is a chronic disease that is the most common joint disorder in China. Knee osteoarthritis (OA) occurs when the protective cartilage on the end of bones wears away. The bones in the knee then rub against one another, causing stiffness, pain and a reduction in the range of movement. It can affect the quality of life, and may even lead to depression. The usual treatment of knee OA usually includes medications, physical therapy and other alternative medical interventions. Although oral analgesics (painkillers taken by mouth), such as nonsteroidal anti-inflammatory drugs (NSAIDs), can achieve moderate reduction of pain and slight functional improvement, they have substantial limitations because they might not provide sufficient joint pain relief, often induce gastrointestinal discomfort, and can adversely interact with other drugs. Physical therapy and other alternative medical interventions are effective but their effects do not last long. There are surgical interventions with arthroscopic lavage and debridement for refractory joint pain (when the joint is washed out to remove any fluid and loose debris in the joint is removed) when medical therapies fail, but the benefits of these procedures are still being debated. As well, patients are not always willing to consider joint-replacement surgery when knee OA symptoms persist. Under such conditions, the potential treatment may switch to therapeutic exercise plus intra articular injection (an needle into the joint) of BoNT-A (a type of toxin that can help the pain) or hyaluronate (a type of sodium salt of hyaluronic acid). BoNT-A has shown to lead to significant improvement in pain and function and is safe to use in previous report. Hyaluronate injection is the current standard of care for knee OA. The aim of this study is to see if pain and dysfunction caused by knee OA could be alleviated by a combined effect of medicine and therapeutic exercise, without changes of knee joint structure.

Who can participate?

Adults aged 18 and older who have knee OA

What does the study involve?

Participants are randomly allocated to one of three groups. Those in the first group receive an injection of BoNT-A. Those in the second group receive hyaluronate and those in the last group receive a saline injection. This is done once at the first visit. Participants are given an exercise to do for eight weeks. Participants are allowed up at the end of week four and eight to assess the treatment on their OA symptoms.

What are the possible benefits and risks of participating?

Participants may benefit from improvements in the pain and function of the knee joint. There are no risks with participating.

Where is the study run from?

Yue Bei People's Hospital (China)

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

January 2016 to December 2016

Who is funding the study?

Yue Bei People's Hospital (China)

Who is the main contact?

Dr Xiao Bao

Contact information

Type(s)

Scientific

Contact name

Dr Xiao Bao

Contact details

Yue Bei People's Hospital
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512025

Additional identifiers

Protocol serial number

2015CX/K025

Study information

Scientific Title

The effect of intraarticular botulinum toxin type A, hyaluronate and saline injection plus therapeutic exercise on knee osteoarthritis: a randomized controlled trial

Study objectives

Pain and dysfunction of knee OA could be alleviated by a combined effect of medicine and therapeutic exercise, without changes of knee joint structure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Yue Bei People's Hospital, 30/06/2015, ref: 2015CX/K025

Primary study design

Interventional

Study design

Single-blind randomized controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Patients with knee osteoarthritis

Interventions

Participants are randomly allocated to receiving either an injection of BoNT-A (100U diluted with 2.5 ml saline), receiving hyaluronate (2.5 ml) or receiving saline (2.5 ml) (control) one time. All participants received the therapeutic exercise after injection for up to eight weeks.

All assessments were made at end of four and eight week to assess the outcomes of the treatment on the participants symptoms.

Intervention Type

Drug

Primary outcome(s)

1. Pain stiffness and physical function is measured using the Western Ontario and McMaster Universities Osteoarthritis Index questionnaire score (WOMAC) at baseline, week four and eight
2. Pain is measured using the Visual Analogue Scale (VAS) at baseline, week four and eight
3. Medical outcomes are assessed using the Medical outcomes study 36-item health survey (SF-36) at baseline, week four and eight

Key secondary outcome(s)

Functional outcomes are measured using x-rays and MRI at baseline and week eight.

Completion date

30/12/2016

Eligibility

Key inclusion criteria

1. Mentally intact that were able to follow 2-step commands
2. Radiographic OA severity grade of 3 or above for the knee joint on the Kellgren-Lawrence scale 16 and pain visual analogue scale score ≥ 6 after Walking 100m continuously on level ground
3. Failure of physical therapy and/or medicine treatment in the last 3 months
4. Involvement of unilateral knee joint
5. Aged 18 and older

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Received an intraarticular (IA) injection into the affected knee within 3 months before the initial evaluation
2. Disease complications such as rheumatoid arthritis, tumors and any non-arthritic trauma to the affected knee in last 3 months
3. Severe cardiac, liver and kidney function deficiency

Date of first enrolment

10/01/2016

Date of final enrolment

30/08/2016

Locations**Countries of recruitment**

China

Study participating centre

Yue Bei People's Hospital

No. 133 HuiMin Road

GuangDong

Shao Guan

China

512025

Sponsor information

Organisation

Yue Bei People's Hospital

ROR

<https://ror.org/0149pmh27>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Yue Bei People's Hospital

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository at Yue Bei People's Hospital.

IPD sharing plan summary

Stored in repository