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The effect of intra-articular hyaluronate and tramadol injection on patients with adhesive capsulitis of the shoulder

Submission date
24/05/2016

Recruitment status
No longer recruiting

Registration date
25/05/2016

Overall study status
Completed

Last Edited
24/07/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Adhesive capsulitis (also known as frozen shoulder) is a condition that leads to pain and stiffness of the shoulder. Clinical studies have reported the safety and effectiveness of injecting hyaluronate into the shoulder joint of patients with adhesive capsulitis. The aim of this study is to assess the effectiveness of a hyaluronate and tramadol injection for adhesive capsulitis of the shoulder.

Who can participate?
Patients with adhesive capsulitis of the shoulder

What does the study involve?
Participants are randomly allocated to the hyaluronate group or the tramadol group. Hyaluronate group members receive five weekly hyaluronate injections. Tramadol group members receive three weekly hyaluronate and tramadol injections, and then two weekly injections of hyaluronate. Range of motion of the shoulder joint and shoulder pain are assessed at the start of the study and 1, 2, 3, 4, and 6 weeks after the first injection.

What are the possible benefits and risks of participating?
Participating helps us to find more effective treatments and does not exceed the minimum risk that may arise in day-to-day treatment.

Where is the study run from?
Soonchunhyang University Hospital (South Korea)

When is the study starting and how long is it expected to run for?
June 2014 to April 2015

Who is funding the study?
Soonchunhyang University (South Korea)

Who is the main contact?
Prof. Ki Young Oh

Contact information

Type(s)
Scientific

Contact name
Prof Ki Young Oh

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SCH-2014-0001

Study information

Scientific Title
The effect of intra-articular hyaluronate and tramadol injection on patients with adhesive capsulitis of the shoulder: a single-blind randomised control trial

Study objectives
More significant changes occur in pain, ROM, and function of shoulder joints when hyaluronate and tramadol are injected together into the joints as treatment for adhesive capsulitis of the shoulder than injected hyaluronate alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Institutional Review Board of Soonchunhyang University Hospital, March 2014

Study design
Single-blind randomised control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Adhesive capsulitis of shoulder

Interventions
The control group (hyaluronate group) was injected only with hyaluronate (Hyal Shin Poong, PhD, Korea, 2.5-mL injection, 1% hyaluronan, molecular weight 940–1,020 kDa) five times in 1-week intervals.

The experimental group (tramadol group) received hyaluronate and tramadol (Tridol Shin Poong, PhD, Korea, 100 mg, 1-mL injection) 50-mg injections three times, and then they received two injections of only hyaluronate afterward. Intra-articular injection was administered by one doctor using the posterior approach

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hyaluronate, tramadol

Primary outcome measure
Visual Analog Scale (VAS), passive range of motion (PROM) of the shoulder joint, and Shoulder Pain and Disability Index (SPADI) scores were assessed at baseline and weeks 1, 2, 3, 4, and 6 after the initial injection.

Secondary outcome measures
N/A

Overall study start date
01/06/2014

Completion date
01/04/2015

Eligibility

Key inclusion criteria
1. Patients who visited the Outpatient Clinic at Soonchunhyang University Hospital
2. Pain and limited movement of the shoulder joints

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Total final enrolment
30

Key exclusion criteria
1. Trauma
2. Stroke
3. Endocrine diseases
4. Arthritis in the shoulder
5. They had been administered an MAO (Monoamin monoamine oxidase) inhibitor during the past 2 weeks
6. They had hypersensitivity to opioids
7. They had received an intra-articular injection in the shoulder during the past 6 months
8. They had undergone other surgeries
9. They had been experiencing symptoms for more than 9 months
10. Ultrasonography showed a full-thickness tear in some tendons of the rotator cuff

Date of first enrolment
01/06/2014

Date of final enrolment
01/02/2015

Locations

Countries of recruitment
Korea, South

Study participating centre
Soonchunhyang University Hospital
Korea, South
31151

Sponsor information

Organisation
Soonchunhyang University (South Korea)

Sponsor details
Bongmyeong-dong
Dongnam-gu
Cheonan-si
Chungcheongnam-do
Cheonan
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330-721

Sponsor type
University/education

ROR
https://ror.org/04q78tk20

Funder(s)

Funder type
University/education

Funder Name
Soonchunhyang University

Alternative Name(s)
, , SCH

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Korea, South

Results and Publications

Publication and dissemination plan
I hope to publish the results within this year (2016)

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/08/2017	24/07/2020	Yes	No