ISRCTN18380042 https://doi.org/10.1186/ISRCTN18380042

Subacromial hyaluronic acid injections perform better when combined with exercise-based rehabilitation in the treatment of subacromial impingement syndrome

Submission date
31/10/2024

Recruitment status
No longer recruiting

Registration date
21/11/2024

Overall study status
Completed

Last Edited
21/11/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study investigates the effectiveness of combining two treatments for shoulder impingement syndrome (SIAS): subacromial injections of hyaluronic acid (HA) and a specific exercise-based rehabilitation (EBR) program. Shoulder impingement syndrome causes shoulder pain due to the compression of soft tissues around the shoulder joint. This study aims to see if using HA injections alone or with EBR provides better outcomes in terms of pain relief and functional improvement.

Who can participate?
Adults aged 18 years old and over diagnosed with grade I or II SIAS were eligible to participate. Participants needed to be experiencing mild to moderate shoulder pain as confirmed by specific clinical and imaging tests. Patients with severe conditions, prior shoulder surgeries, or specific exclusions such as cognitive impairment were not eligible.

What does the study involve?
Participants were divided into two groups. The first group received three HA injections into the shoulder over six weeks. The second group received the same HA injections along with an intensive, supervised EBR program, consisting of five sessions per week. Both treatments were non-surgical and aimed at relieving pain and improving shoulder function.

What are the possible benefits and risks of participating?
Participants may experience reduced shoulder pain and improved shoulder movement and strength. HA injections are generally safe, with a low risk of adverse reactions. Exercise therapy may help improve muscle balance and strength, potentially enhancing overall shoulder health. No adverse events were observed during the study for either treatment group.

Where is the study run from?
The study was conducted in a clinical research setting following ethical standards and guidelines.

When is the study starting and how long is it expected to run for?
The study was conducted over several months from June 2011 to July 2013, with participants followed up at 1, 3, and 6 months to assess the effectiveness of the treatments.

Who is funding the study?
This clinical trial does not incur additional costs beyond those associated with standard clinical practice. The interventions and assessments included in the trial align with routine care procedures, ensuring that participation does not impose extra financial burdens on the healthcare system or patients at Agostino Gemelli University Polyclinic.

Who is the Main Contact?
Prof. Giuseppe Milano, giuseppe.milano@unibs.it

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Giuseppe Milano

ORCID ID
https://orcid.org/0000-0001-6040-9623

Contact details
Viale Europa 11
Brescia
Italy
25123
+39 030 393981
giuseppe.milano@unibs.it

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Comparison between isolated hyaluronic acid injection therapy and combined physical therapy in the treatment of chronic rotator cuff tendinopathy. A randomized prospective clinical study.

Acronym
HA-FKT-SHD

Study objectives
The purpose of the present study was to assess the efficacy of HA subacromial injections isolated or combined with individualized exercise-based rehabilitation (EBR) programs as therapeutic regimens for the treatment of SIAS. The study hypothesized that the difference between the two therapeutic regimens is significant.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/06/2011, Catholic University of The Sacred Heart Faculty of Medicine and Surgery "Agostino Gemelli" (Università Cattolica Del Sacro Cuore Facoltà Di Medicina E Chirurgia "Agostino Gemelli") (Largo Francesco Vito 1, Rome, 00168, Italy; +390630151; comitatoetico.lazioarea3@policlinicogemelli.it), ref: P/480/CE/2011

Study design
Blinded prospective randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Subacromial impingement syndrome

Interventions
Patients selected for the study were carefully informed of the expected benefits of the procedures involved. Patients who accepted our invitation to be enlisted in the study signed a disclosure agreement form. Randomization was conducted using a computerized random assignment system. This approach ensures a balanced distribution between the intervention and control groups, minimizing the risk of selection bias.

Patients from group 1 (HA group) underwent treatment by 3 subacromial injections (one every 2 weeks) of high-molecular-weight HA (Orthovisc 2 ml; 15 mg/ml; Anika Therapeutics Inc., Bedford, MA), supplied as sterile, pre-filled syringes. Injections were administered in aseptic conditions with a 21-gauge needle by an experienced physician unaware of the patient’s treatment allocation. In group 2 (HA + EBR group), patients underwent 3 subacromial injections on the affected shoulder by the same protocol used in group 1; furthermore, they underwent a program of five sessions per week of supervised EBR for a total of 20 treatment sessions in a month. Patients were instructed to avoid any additional therapeutic measure for pain management (pharmacological or physical) during the treatment and for the subsequent 6 months. The patients were not instructed during the study about activity or home exercise programs during or following supervised therapy. Follow-up assessments were conducted at 1, 3, and 6 months.

Intervention Type

Procedure/Surgery

Primary outcome(s)
Disease-specific health-related quality of life (QoL) measured using the nationally validated versions of the DASH (Disability of Arm, Shoulder, and Hand) questionnaire in its short version (Quick-DASH) at 1, 3, and 6 months

Key secondary outcome(s))
Working capacity measured using the DASH work module (Work-DASH) and a functional assessment of the shoulder with the Constant-Murley score (CMS) at 1, 3, and 6 months

Completion date
01/07/2013

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. A diagnosis of SIAS grade I or II according to Neer's classification as diagnosed on clinical examination and imaging studies

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
160

Key exclusion criteria
1. Calcific tendonitis of the rotator cuff and full-thickness rotator cuff tear
2. Shoulder stiffness
3. Previous fractures and/or surgeries to the same shoulder
4. Long-lasting history of shoulder pain (exceeding 6 months) treated with steroids or NSAIDs
5. Treatment of shoulder pain by EBR or shoulder injections with HA or steroids during the last 6 months
6. Shoulder involvement in congenital or acquired inflammatory or neurological disorders
7. Cognitive or psychiatric impairment
8. Unwillingness or inability to sign informed consent

Date of first enrolment
01/07/2011

Date of final enrolment
01/07/2012

Locations

Countries of recruitment
Italy

Study participating centre
U.O. di Ortopedia – Policlinico Universitario A. Gemelli, Roma
Largo Agostino Gemelli, 8
Rome
Italy
00136

Sponsor information

Organisation
Agostino Gemelli University Polyclinic

ROR
https://ror.org/00rg70c39

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Agostino Gemelli University Polyclinic

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof. Giuseppe Milano, giuseppe.milano@unibs.it. Consent was obtained from all participants in the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes