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Organ for Norsk forening for ultralyddiagnostikk

Ultrasound guided lavage with corticosteroid injection versus sham lavage with and without corticosteroid injection for calcific tendinopathy of shoulder: randomised double blinded multi-arm study

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Objective

To compare treatment effects between ultrasound-guided lavage with corticosteroid injection and sham lavage with and without corticosteroid injection in patients suffering from calcific tendinopathy of the shoulder.

Design

Pragmatic, three-arm, parallel group, double-blinded, sham-controlled, randomized, superiority trial with repeated measurements over 24 months.

Setting

Six hospitals in Norway and Sweden.

Participants

220 adults with calcific tendinopathy of the shoulder, persistent for at least three months.

Interventions

Ultrasound guided deposit lavage plus subacromial injection of 20 mg triamcinolone acetonide and 9 ml 1 % lidocaine hydrochloride (lavage + steroid), sham lavage plus subacromial injection of 20 mg triamcinolone acetonide and 9 ml 1 % lidocaine hydrochloride (sham lavage + steroid), or sham lavage plus subacromial injection of 10 ml 1 % lidocaine hydrochloride (sham). All patients received a physiotherapeutic treatment regimen consisting of four home exercises.

Main outcome measures

The primary outcome was the result on the 48 point scale (0 = worst; 48 = best) of the Oxford Shoulder Score (OSS) at 4-month follow-up. Secondary outcomes included measurements on the short form of the Disabilities of the Arm, Shoulder and Hand score (QuickDASH) and of pain intensity up

to 24 months. The influence of the size of the deposit at baseline and of the persistence or disappearance of the deposit was investigated.

Results

Data from 218 (99%) participants were included in the primary analysis. Differences between groups on the OSS at four months were not significant: Lavage + steroid versus sham 0.2 (95 % confidence interval -2.3 to 2.8; $P = 1.0$); sham lavage + steroid versus sham 2.0 (95 % confidence interval -0.5 to 4.6; $P = 0.35$); lavage + steroid versus sham lavage + steroid -1.8 (-4.3 to 0.7; $P = 0.47$). After four months, 143 patients with insufficient treatment effect received supplementary treatment. At 24 months none of the study procedures was superior to sham. No serious adverse events were reported.

Conclusions

This study found no benefit for ultrasound-guided lavage with a corticosteroid injection or for sham lavage with a corticosteroid injection compared to sham treatment in patients with calcific rotator cuff tendinopathy of the shoulder.

Trial registration

NCT02419040/EudraCT 2015-002343-34; Ethical committee Norway 2015-002343-34; Ethical committee Sweden 2015/79-31; Clinicaltrials.gov NCT02419040.