Corticosteroid injections for tennis elbow (Protocol)

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Corticosteroid injections for tennis elbow

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The objective of this systematic review is to determine the short, intermediate and long-term effectiveness of corticosteroid injections for lateral epicondylitis.
BACKGROUND

Lateral epicondylitis (tennis elbow) is a common complaint in primary care. It is considered to be an injury following mainly minor and often unrecognised trauma (microtrauma), involving the extensor muscles of the forearm (Murtagh 1988, Ernst 1994). Several underlying pathological mechanisms will be indicated, but the ailment is considered by most authors to be a lesion of the common extensor muscles at the lateral humeral epicondyl, specifically the tendon of the extensor carpi radialis brevis (Murtagh 1988, Chard 1989, Ernst 1994). Runge 1973 first described this condition, but the name derives from Morris’ description of “lawn tennis arm” in 1982.

In general practice, the incidence of lateral epicondylitis is estimated at seven per 1000 patients per year (Verhaar 1992, Miedema 1994). In Sweden the overall prevalence of lateral epicondylitis varies between 1% and 3%, but this figure increases to 10% for females between 42 years and 46 years of age. The annual incidence of this complaint is between 1% and 3% in the general population (Allander 1974, Chard 1989, Chop 1989). The duration of a typical episode of lateral epicondylitis is reported to be between 6 months and 2 years (Murtagh 1988). Lateral epicondylitis results in absenteeism in 10% to 30% of all patients with an average duration of 12 weeks (Verhaar 1992, Blanken 1981, Schonk 1985).

In Dutch primary care approximately 14 to 38 per cent of all patients with lateral epicondylitis are treated with corticosteroid injections. (Verhaar 1992, Miedema 1994) The effect of corticosteroid injections is exerted by suppressing or dispersing the granulomatous response in traumatised tissue. The anti-inflammatory effects of steroids injections are believed to relieve pain and diminish disability (Gray 1983, Goldie 1972).

In an attempt to systematically summarise the available evidence, Labelle 1992 intended to perform a quantitative meta-analysis of 17 (randomised) controlled trials on various treatments for lateral epicondylitis, including 5 (randomised) clinical trials on treatment by steroid injection. However, they decided that it was impossible to statistically pool the studies because of the considerable variation in treatments, selection criteria and outcome measures. Because of the poor quality of methods and the contradictory results Labelle 1992 concluded that there was insufficient scientific evidence for any particular type of treatment for lateral epicondylitis. The review by Labelle 1992 only covered the Randomised Controlled Trials (RCTs) and Clinically Controlled Trials (CCTs) indexed in MEDLINE during 1966-1990, and included only studies published in French or English. According to the current state-of-the-art a more comprehensive search strategy is strongly advisable (Greenhalgh 1997, Meade 1997, Meade 1997). Thus, RCTs indexed in other bibliographical databases, non-indexed RCTs, RCTs published before 1966 and after 1990 and trials published in other languages than English should be included in a review on this topic, as exclusion of these trials might influence the results and conclusions of the review (Gregoire 1995, Egger 1997). Raining from pooling the data, as Labelle did, is only one of the options available for dealing with the insufficient methodological quality of RCTs (Detsky 1992). There are other ways of incorporating methodological quality in the meta-analysis of RCTs.

Assendelft 1996 performed a more comprehensive systematic overview. He reviewed 11 RCTs and concluded that the existing evidence on the effectiveness of corticosteroid injection for lateral epicondylitis is not conclusive. The methodological quality of the studies was moderate and most of the studies were conducted in secondary care, whereas many patients are treated in a primary care setting. However, Assendelft concluded that corticosteroid injections appear to be relatively safe and seem to have a short-term effect (2-6 weeks) when administered in a secondary care setting. Although the effectiveness of corticosteroid injections for lateral epicondylitis has been addressed in two previous systematic reviews (Labelle 1992, Assendelft 1996), a new systematic review according to the current state-of-the-art can provide additional relevant information. Conforming with the methods and criteria of the Cochrane Collaboration, we will use explicit methods for the selection of randomised trials and assessment of quality, and we will refrain from using language restrictions. Separate analyses of subsets of studies will be considered, evaluating the influence of relevant prognostic factors, type of control intervention, internal validity of the study, type of outcome measures, and timing of follow-up on the effectiveness of corticosteroid injections for lateral epicondylitis.

OBJECTIVES

The objective of this systematic review is to determine the short, intermediate and long-term effectiveness of corticosteroid injections for lateral epicondylitis.

METHODS

Criteria for considering studies for this review

Types of studies

Treatments will be allocated by a random procedure (Schulz 1994). The word “random” or “randomised” should be mentioned. No restrictions will be made concerning the language of publication (Moher 1996, Gregoire 1995).
Types of participants
The study will include patients with lateral epicondylitis or lateral elbow pain, increased by pressure on the lateral epicondyle, and pain on resisted dorsiflexion of the wrist. Studies containing patients with other diagnoses are only eligible if the results from patients with lateral epicondylitis are presented separately.

Types of interventions
At least one treatment will include corticosteroid injection. Corticosteroid injection will be contrasted with other conservative treatments: 1) injection with another liquid (corticosteroid or anaesthetic); 2) placebo; 3) no treatment (waiting list control group); or 4) "other conservative treatment" (none of the previously mentioned).

Types of outcome measures
At least one clinically relevant outcome measure (pain, global measure of improvement, elbow specific functional status, grip strength, generic functional status, or patient satisfaction) will be included. Outcome assessment will be at least 1 day (24 hours) after the first injection.

Search methods for identification of studies
One reviewer (NS) will search computerised bibliographical databases (MEDLINE January 1966 - May 1999, EMBASE January 1988 - May 1999, CINAHL January 1982 - May 1999) without language restrictions, of the Cochrane Collaboration search strategy, which aims to identify all randomised controlled trials (Mulrow 1997). The search strategy used to identify RCTs will include the following keywords: randomised controlled trials, controlled clinical trials, random allocation, double blind, single blind, experiments, multicenter trials and related free text words. Subject headings and textwords used to identify lateral epicondylitis will be: elbow, elbow joint, tendinitis, tennis elbow, and epicondylitis. Subject headings and textwords to identify the interventions will be: intra articular, (gluco) corticosteroid injection, local anaesthetic, conservative, local infiltration, (methyl) prednisolone, triamcinolone, and (hydro) cortisone. The Cochrane Controlled Trial Register of the Cochrane Library will be searched for RCTs on epicondylitis (Cochrane 1999). In order to retrieve additional references an additional search for systematic reviews will be carried out in EMBASE and MEDLINE (Hunt 1997). Furthermore, the Current Contents database will be searched, and the references from all retrieved articles will be screened (citation tracking).

To determine whether a study should be included, the title, keywords and abstract of all identified hits of the electronic bibliographical databases will be assessed by two reviewers (DW and NS). They will decide independently the eligibility of the article according to the predetermined selection criteria. If there is any doubt, the article will be retrieved, blinded for author, journal and year of the trial by an independent assistant and read by the reviewers. Disagreements between the reviewers about the eligibility of the articles will be discussed in a consensus meeting. In case of non-consensus between the reviewers, a third reviewer (LMB) will decide if the study is eligible.

Database: MEDLINE <1966 to July 1999>
Set Search
1 randomized controlled trial.pt.
2 controlled clinical trial.pt.
3 randomized controlled trials.sh.
4 random allocation.sh.
5 double blind method.sh.
6 single blind method.sh.
7 1 or 2 or 3 or 4 or 5 or 6
8 (animal not (human and animal)).sh.
9 7 not 8
10 clinical trial.pt.
11 exp clinical trials/
12 (clin$ adj25 trial$).ti,ab.
13 ((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).ti,ab.
14 placebo.sh.
15 placebo$.ti,ab.
16 random$.ti,ab.
17 research design.sh.
18 volunteer$.ti,ab.
19 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
20 19 not 8
21 20 not 9
22 9 or 21
23 tendinitis.sh.
24 elbow.sh.
25 elbow joint.sh.
26 24 or 25
27 23 and 26
28 tennis elbow.sh
29 27 or 28
30 epicondylitis.tw.
31 elbow.tw.
32 29 or 30 or 31
33 32 and 34
34 33 not 32
35 intra-articular.tw.
36 glucocorticosteroid injection.tw.
37 glucocorticoids/
38 local anaesthetic$tw.
39 injection$sh.
40 corticosteroid$tw.
41 steroid$tw.
42 steroid$sh.
Data collection and analysis

The criteria used for methodological quality assessment is given in Table 1. It consists of internal validity criteria, descriptive criteria and statistical criteria. The descriptive and statistical criteria refer to the external validity of the study and are used to identify homogeneous subgroups and conduct sensitivity analyses. This criteria list is a modified version of a list that has already been used in a number of systematic reviews in the field of musculoskeletal disorders (van der Windt 1999, van der Heijden 1997, van Tulder 1997, van Tulder 1999, de Vet 1997) and includes all criteria of the list of Jadad 1996, Schulz 1994 and Verhagen 1998. For this review, the methodological criteria will be adjusted to later condylitis and corticosteroid injections. We will assess the validity and relevance for each outcome measure. We will assess the quality of the included RCTs using an additional tool (Jadad 1996).

Table 1: Criteria for the methodological assessment of randomised clinical trials†

<table>
<thead>
<tr>
<th>Validity criteria (full study)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>43</strong> or<strong>43</strong></td>
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<tr>
<td><strong>44</strong> Conservative$$.tw.$$</td>
</tr>
<tr>
<td><strong>45</strong> Anesthetics, local/</td>
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<tr>
<td><strong>46</strong> Anti-inflammatory agents, steroidal/</td>
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<tr>
<td><strong>47</strong> Steroidal$.tw.$$</td>
</tr>
<tr>
<td><strong>48</strong> Inject$.tw.$$</td>
</tr>
<tr>
<td><strong>49</strong> Local infiltration.tw.$$</td>
</tr>
<tr>
<td><strong>50</strong> Prednisolone.tw.$$</td>
</tr>
<tr>
<td><strong>51</strong> Methylprednisolone.tw.$$</td>
</tr>
<tr>
<td><strong>52</strong> Cortisone.tw.$$</td>
</tr>
<tr>
<td><strong>53</strong> Hydrocortisone.tw.$$</td>
</tr>
<tr>
<td><strong>55</strong> Or/34-54</td>
</tr>
<tr>
<td><strong>56</strong> 33 and 55</td>
</tr>
</tbody>
</table>

**Database: EMBASE <1966 to July 1999>**

**Set Search**

1 Clinical article.sh.
2 Clinical study.sh.
3 Clinical trial.sh.
4 Controlled study.sh.
5 Randomized controlled trial.sh.
6 Major clinical study.sh.
7 Double blind procedure.sh.
8 Multicenter study.sh.
9 Single blind procedure.sh.
10 Phase 3 clinical study.sh.
11 Phase 4 clinical study.sh.
12 Crossover procedure.sh.
13 Placebo.sh.
14 Or/1-13
15 Allocat$.ti,ab.
16 Assign.ti,ab.
17 Blind$.ti,ab.
18 (Clinical$ adj25 (Study or trial)).ti,ab.
19 Compare$:ti,ab.
20 Control$:ti,ab.
21 Cross-over.ti,ab.
22 Factorial$:ti,ab.
23 Follow-up.ti,ab.
24 Placebo$:ti,ab.
25 Prospective$:ti,ab.
26 Random$:ti,ab.
27 ((Single$ or Double$ or Trebl$ or Trip1$) adj25 (Blind$ or Mask$)):ti,ab.
28 Trial$.ti,ab.
29 (Versus or vs).ti,ab.
30 Or/15-29
31 14 or 30
32 Human.sh.
33 Tendinitis.sh.
34 Elbow.sh.
35 Elbow joint.sh.
V5 Co-interventions: reported for each group separately
V6 Adherence to interventions: > 70% in intervention group(s), with exception of waiting list and control group.
V7 Care provider blinded
V8 Patient blinded
V9 Withdrawals and drop-outs: < 20% for short term follow-up (< 6 weeks) and < 30% for intermediate term (6 weeks < 6 months) and long term follow-up (> 6 months) and no substantial bias (inequality between groups; reasons for withdrawal/drop-out reported)
V10 Identical timing of outcome assessment for all intervention groups
V11 Intention-to-treat analysis
Validity criteria (per outcome measure)*
V1 Outcome assessment blinded
V2 Valid outcome measure
V3 Relevant outcome measure
Descriptive criteria
D1 Specification of eligibility criteria
D2 Baseline similarity regarding age, duration of complaints, neck and shoulder complaints, and baseline main outcome measure(s)*
D3 Description of interventions: description of dosage, number of treatments (injections), frequency and amount of liquid for both intervention groups.
D4 Adverse effects described and attributed to allocated treatment, or explicit report of ‘no adverse effects’
D5 Short term follow-up: outcome assessment at the end of the intervention period (or < 6 weeks)
D6 Intermediate term follow-up: outcome assessment > 6 weeks and < 6 months
D7 Long term follow-up: outcome assessment > 6 months after randomisation
Statistical criteria
S1 Sample size: to be presented at randomisation and for main outcome of moment assessment
S2 Presentation of point estimates and distribution measures, for each important outcome measure separately
* = Assessed for each outcome measure: pain, global measure of improvement, elbow specific functional status, grip strength, patient satisfaction, and generic functional status
† The criteria and original quality assessment forms are available on request from the primary author
All articles eligible for the review will be blinded for authors, journal and year of the trial. Included articles will be independently assessed on methodological quality by two blinded reviewers (NS and WJJA). The success of blinding will be determined by asking both reviewers to attempt to identify the author(s), journal and year of the trial. Initial disagreement between the reviewers about the assessment of the methodological quality of the articles will be calculated per criterion and expressed as percentage agreement and as a kappa coefficient (Cohen 1960, Brennan 1992). In a consensus meeting, disagreements about the assessment of the methodological quality of the articles will be discussed. If consensus cannot be reached, a third reviewer (DW) will make the final decision. For studies published in languages other than English, German or Dutch, the help of a native speaker or translator will be required. Since assessment by different reviewers might affect the accuracy of quality assessment and data extraction, these studies will be analyzed in a sensitivity analysis.
To determine the internal validity of the study, for each validity criterion the presence of sufficient information and the likelihood of potential bias will be evaluated. If sufficient information is available and bias is considered to be unlikely, the criterion will be rated positive (‘yes’). If bias is considered to be likely, the criterion will be rated negative (‘no’). When insufficient information is given, the criterion will be rated as inconclusive (‘don’t know’). A total score for internal validity of the study (‘study validity score’) will be calculated, by summing the number of positive criteria. Equal weights will be applied, resulting in a validity score with a range of 0 to 11, higher scores indicating lower likelihood of bias. Additional points will be assigned for adequate blinding of measurement, and for validity and relevance of the outcome measure. Two blinded reviewers (NS and WJJA) will independently extract the data regarding using a predefined form, the interventions, type of outcome measures, follow-up, lost to follow-up and results. The various outcome measures will be presented separately. The results of each RCT will be expressed as relative risks with corresponding 95% confidence intervals (95% CI) for dichotomous data, and as a weighted mean difference at follow-up and standard deviation for continuous data (Rosenthal 1994, Mulrow 1997, Lau 1997). For continuous outcomes, results for differences in improvement will be used in preference to differences between post-treatment values. Analyses will be performed for the short-term, intermediate-term and long-term effect of corticosteroid injections for lateral epicondylitis separately.
Pre-planned stratified analyses are:
1) Contents of intervention groups: Index group corticosteroid injection versus control group a) other corticosteroid injection, b) injection with anaesthetic, c) other conservative treatment (e.g., oral medication or physiotherapy), d) placebo treatment and e) no treatment / waiting list;
2) Validity score: Low validity trials versus high validity trials; (Moher 1998) Cut-off point is the median of the validity score (max. 11 points) of all RCTs;
3) Prognostic factors: a) Lateral epicondylitis with additional neck
and shoulder complaints versus lateral epicondylitis without neck or shoulder complaints and b) duration of elbow complaints: acute (<6 weeks), subacute (6 weeks to 13 weeks), chronic (>13 weeks). As reports on subgroup analyses within trials are often lacking, these stratified analyses will be conducted using between-study comparisons.

ACKNOWLEDGEMENTS

The reviewers would like to thank the Cochrane Musculoskeletal Group Editorial Team for their helpful comments in reviewing this document. Also to thank Heather Broughton and Jim Davies for their editorial suggestions.

REFERENCES

Additional references

Allander 1974

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Beckerman 1993

Blanken 1981

Brennan 1992

Chard 1989

Chop 1989

Cochrane 1999
Cochrane Controlled Trial Register. The Cochrane Library 1999, issue 2.

Cohen 1960

de Vet 1997

Detsky 1992

Egger 1997

Ernst 1994

Goldie 1972

Golding 1991

Golding 1992

Gray 1983

Greenhalgh 1997

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Gregoire 1995

Hunt 1997

Jadad 1996

Labelle 1992

Lau 1997

Meade 1997

Miedema 1994

Moher 1996

Moher 1998

Morris 1982

Mulrow 1997

Murtagh 1988

Rosenthal 1994

Runge 1973

Schonk 1985

Schulz 1994

van der Heijden 1997

van der Windt 1999

van Tulder 1997

van Tulder 1999

Verhaar 1992

Verhagen 1998

* Indicates the major publication for the study.
**WHAT'S NEW**

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**HISTORY**

Protocol first published: Issue 1, 2000

**DECLARATIONS OF INTEREST**

None Known

**SOURCES OF SUPPORT**

**Internal sources**
- Department of Epidemiology and Preventive Medicine, Australia.
- Institute for Research in Extramural Medicine, Netherlands.
- Department of General Practice, Dutch Cochrane Centre, Academic Medical Centre, Netherlands.
- Staffordshire Rheumatology Centre, Stroke-on-Trent, UK.

**External sources**
- No sources of support supplied