MRI for Lateral Elbow Pain: Comparison of Affected and Unaffected Elbows

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The purpose of the current study is to compare MRI findings between affected and unaffected elbows in patients with clinically diagnosed unilateral lateral elbow painGiven the considerable number of degenerative changes in asymptomatic elbows...

Ethical review	Approved WMO
Status	Pending
Health condition type	Tendon, ligament and cartilage disorders
Study type	Observational non invasive

Summary

ID

NL-OMON33699

Source
ToetsingOnline

Brief title
MRI for lateral elbow pain.

Condition

- Tendon, ligament and cartilage disorders

Synonym
lateral elbow pain, tennis elbow

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Lateral elbow pain, MRI, symptomatic versus asymptomatic, tenniselbow

Outcome measures

Primary outcome

Primary Study Question (Null hypothesis):

Among those with changes on MRI, both symptomatic and asymptomatic elbow are equally likely to have a defect (group partial and complete). All or none (defect or no defect) in 2 groups.

Secondary outcome

Secondary Study Questions:

Among patients with changes on MRI of the symptomatic side, the other side (symptomatic or asymptomatic) has MRI changes c/w lateral epicondylosis. All or none (MRI findings or not) in 2 groups

Study description

Background summary

Enthesopathy of the origin of the extensor carpi radialis brevis (ECRB) is also know as lateral elbow pain, lateral epicondylitis, lateral epicondylosis, or tennis elbow. Lateral epicondylosis may be the most prevalent of many common degenerative disorders of muscle and ligament insertions that occur in middle-aged humans, and annual incidence in general population is approximately 1-3%. Lateral elbow pain is a benign and self-limiting condition. Symptoms will usually recover over the course of approximately twelve to eighteen months. The role of operative treatment is incompletely defined.
The pathological changes in the origin of the ECRB appear as edema, partial thickening, and tendon defects (often labeled as partial or complete *tears*) on Magnetic Resonance Imaging (MRI). In addition, edematous changes in the anconeus muscle have been reported. Asymptomatic pathological changes on MRI of the contralateral arm are common in patients with rotator cuff tendinopathy and there is some evidence that the same may be true for lateral epicondylosis.

Studies have described similar changes on MRI of asymptomatic elbows as well. For instance, Martin et al. reported changes on MRI in 3 of 16 individuals (19%) without symptoms of lateral elbow pain. Two previous studies suggested the presence of degenerative changes in 27% to 54% of asymptomatic elbows as compared to 70% to 100% in symptomatic elbows.
Limitations of these studies include limited power (only 11 and 17 contralateral elbows imaged, with 6 MRI abnormalities in each study), technical issues (lowfield or highfield MRI only), and inclusion of patients with complaints of bilateral elbow pain. To the best of our knowledge, there have been no adequately-powered prospective studies with the primary study objective being a comparison of MRI findings between symptomatic and asymptomatic elbows in unilateral epicondylosis . The purpose of the current study is to compare MRI findings between affected and unaffected elbows in patients with clinically diagnosed unilateral lateral elbow pain.

Study objective

The purpose of the current study is to compare MRI findings between affected and unaffected elbows in patients with clinically diagnosed unilateral lateral elbow pain
Given the considerable number of degenerative changes in asymptomatic elbows reported in previous investigations, it is unclear if such changes explain the symptoms that patients experience. Furthermore, we believe that the finding of a defect or *tear* tends to be overinterpreted and probably does not merit specific treatment. The aim of this research study is to obtain objective data about degenerative changes in the affected and unaffected elbow in patients diagnosed with lateral elbow pain.

Study design

All patients that meet the eligibility criteria will be invited to our outpatient clinic. An independent research fellow not involved with patients* care will explain the study in detail and informed consent will be obtained. It will be explained that participation is voluntary and that subjects can withdraw at any time during the study. Withdrawal will not influence further care and treatment.
C. Study Procedures
Upon consent, demographics (age, gender, and occupation) will be collected and patients will be asked to complete two questionnaires: Questionnaire A (time since onset of symptoms, previous treatment, limb dominance, and a VAS pain scale) and Questionnaire B (the Disabilities of Arm Shoulder and Hand questionnaire (DASH) [36]. In addition, grip strength of both arms will be measured by the independent researcher as the average of three attempts using a handgrip meter (Preston; Jackson, MI, Jamar [34,35],) placed at the third station with the arm at the side, the elbow at 90° flexion, and the forearm and wrist in neutral position. Grip strength of the involved arm will be compared

with the opposite side, and the percentage of grip strength (involved/noninvolved arm) will be calculated.

Subsequently, MRI scans (T1 and T2) will be made of both the affected as the unaffected elbow. The MRI scans will be evaluated by an independent radiologist for presence of edema, partial thickening, microtears, partial or complete tears, avulsion of the common extensor tendon, or any other abnormalities. In addition, the signal intensity of the common extensor tendon will be graded as done in previous studies[16,20]: mild (thickened or thinned tendon, with increased MRI signal), moderate (presence of partial tendon tears), or severe (complete tendon tear or avulsion).

Study burden and risks

not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Lateral elbow pain

Exclusion criteria

Pregnancy, metal parts in the body, Systemic Inflammatory Disease (e.g. Reumatoid Artritis), age younger than 18 years. Patients with a pacemaker.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2009
Enrollment:	26
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL25788.018.08