Groningen Hand and Wrist Injection Therapy Trial (HAWITT).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22395

Source
NTR

Brief title
HAWITT

Health condition

tenosynovitis, trigger finger, trigger digit, carpal tunnel syndrome

Sponsors and support

Primary sponsor: Department of General Practice
University Medical Center
University of Groningen
Source(s) of monetary or material Support: -Fonds Alledaagse Ziekten van het Nederlands Huisartsen Genootschap
-department of general practice, University Medical Center, University of Groningen
-unrestricted educational grant from pharmaceutical company Bristol-Myers, Squibb

Intervention

Outcome measures

Primary outcome

1. Patients perceived recovery (7-points numeric rating scale: from much worse to much better as compared to pre-treatment);

2. Severity of pain/ main complaint (11 point numeric rating scale: 0-10, CTS: severity of symptoms according to the Boston Carpal tunnel questionnaire);

3. TF: triggering and/or clicking and/or locking (4 point ordinal scale: 0= never, 1=incidental, 2=weekly, 3=daily, 4=always);

4. Functional impairment:

a. TF/ MdeQ: Arthitis Impact Measurement Scale 2 (AIMS 2), subitems hand-and finger function;

b. CTS: functional impairment according to the Boston Carpal tunnel questionnaire;

Timing of measurements: 1 week after last injection and follow-up 1,3,6 and 12 months after intervention.

Secondary outcome

1. Occurrence of short and longterm side-effects and serious adverse events: questions regarding the occurrence of steroid-flare, flushes, menstrual abnormalities,hyperglycemia in diabetic patients and questions regarding presence/absence of clinical signs suggesting fat-atrophy, tendon-rupture and median-neuritis (in CTS);

2. Recurrences (when and how many), management of recurrences;

3. Patient satisfaction with injection-therapy (follow-up at 1 month, 7-point numeric scale: 0=very dissatisfied, 6=very satisfied);

4. Treatment-preferences after undergoing treatment (no treatment, physical therapy, wrist-splinting, injection therapy with steroid, operation);

Timing of measurements: 1 week after last injection and follow-up 1,3,6 and 12 months after intervention.

Study description

Background summary

Local injectiontherapy with corticosteroids is an accepted (initial) treatment modality for carpal tunnel syndrome (CTS), trigger finger (TF) and de Quervain's tenosynovitis (MdeQ), with reported longterm (1 year) efficacy of 50-90% (MdeQ and TF) and 50% (CTS). However, all available data originate from specialist clinical centres, no studies concerning

effectiveness of this therapy have been performed so far in general practice.

The HAWITT intervention-study assesses the effectiveness, safety and feasibility of injectiontherapy with triamcinolon-acetonide (1ml=10mg) as compared to placebo-treatment (1ml NaCl 0,9%). Patients will be injected (double-blind) up to two times, after randomization, with either steroids or placebo. One week after each injection clinical findings used as outcome-measurements will be assessed by the treating general practitioner. Follow-up at 1, 3, 6, and 12 months post-treatment will consist of written questionnaires sent to the patient.

Thirty general practices in the northern part of the Netherlands will participate in the HAWITT-trial. A total of 120 patients will be included in the intervention-study (70 CTS, 50 TF/MdeQ). Patients will be followed up for one year; the total duration of the study will be three years (end of trial: December 2006).

Study objective

Local injection therapy with 1ml of triamcinolonacetonide (10mg/ml) provided by a primary care physician is more effective than injection with 1ml NaCl (0,9%) for trigger finger, de Quervain's tenosynovitis and carpal tunnel syndrome.

Study design

N/A

Intervention

1-2 local injections of 1 ml of triamcinolonacetonide (10mg/ml) versus 1 ml of NaCl 0,9% (placebo) one week after inclusion.

Contacts

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Eligibility criteria

Inclusion criteria

Patients in primary care presenting with a clinical diagnosis of trigger finger, de Quervain's tenosynovitis or carpal tunnel syndrome.

Exclusion criteria

1. Minor age;

2. Absolute contra-indication for steroid injection;

3. Prior treatment with steroid injection in the last 6 months or surgical treatment (ever) for same condition at same anatomical site;

4. Traumatic or neoplastic origin of condition;

5. Participant not able to fill in questionnaires;

6. Absence of self-determination;

7. No consent;

8. In carpal tunnel syndrome: thenar atrophy and/or weakness.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2002
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	18-09-2005
Application type:	First submission

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
NTR-new	NL288
NTR-old	NTR326
Other	: N/A
ISRCTN	ISRCTN53171398

Study results

Summary results
N/A