Corticosteroid injections effective for trigger finger in adults in general practice: a double-blinded randomized placebo controlled trial

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Published as:

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Abstract

Objective
To study efficacy and safety of corticosteroid injections for trigger finger (flexor tenosynovitis) in adults in general practice.

Methods
Adult patients presenting with trigger finger were recruited by 21 participating general practitioners. In this randomized placebo controlled double-blinded trial patients were injected locally with one or two injections of 1 ml triamcinoloneacetonide (TCA) or 0.9 % NaCl. Outcomes regarding immediate treatment response, severity of symptoms, functional disability, patient satisfaction and side-effects were measured one week after intervention and during 12 months thereafter.

Results
50 patients were included. Short term outcomes for the TCA- and NaCl-group were respectively: proportion of patients with satisfactory immediate treatment response 16/25 and 5/25 (p<0.0005), patients with reduction in the frequency of triggering 13/24 and 6/22 (p= 0.053), mean difference in severity of pain 4.2 and 0.9 (p<0.0005), patients perceiving improvement 22/25 and 9/25 (p<0.0005) and difference in AIMS-2 score 4.02 and 0.06 (p=0.001) Long term effects could only be assessed by analyzing the cohort of participants who received TCA (as allocated treatment or escape treatment), due to a high proportion of non-responders in the NaCl-group. The short term beneficial effects were maintained during the follow-up phase of 12 months. Patients were satisfied with corticosteroid injection therapy and there were only a few minor side effects.

Conclusions
Local injection with triamcinoloneacetonide is effective and safe for treating trigger fingers as compared to placebo injection. The effects of steroid injections last up to 12 months.

Key words
trigger finger, stenosing tenosynovitis, randomized controlled trial, glucocorticoids, therapy
Introduction

Pathophysiology, epidemiology and treatment options

Tendon entrapment of the finger flexors, also known as trigger finger or stenosing tenosynovitis, is a condition that causes triggering, snapping or locking on flexion of the involved digit. Entrapment results in difficulty flexing or extending the digit and is frequently associated with pain.

The flexor tendon sheet in the finger is a double-walled, connective tissue cylinder that is held in place by five annular (A1-A5) and three cruciform pulleys (C1-C3). The triggering phenomenon is caused by incompatibility between the tendon and its sheet, most probably due to hypertrophy of the first annular pulley (A1). Histologically the A1 pulley demonstrates findings consistent with fibrocartilagenous metaplasia, including more chondrocytes, increased glycosaminoglycan, degenerative changes and proliferation of fibrous tissue. These changes are believed to represent adaptations to shear load. Although trigger finger is also known as tenosynovitis no inflammatory changes were seen in histologic studies.

Trigger finger seems to be a fairly common disorder and has already been described by Notta in 1851. However, surprisingly little is known about incidence and prevalence in the general population or its burden on healthcare. The lifetime prevalence of trigger digit among non-diabetics above age 30 has been estimated at 2.2%. Although a study of 665 workers at a meat packing plant a point prevalence of 14% has been reported, the association between work-related cumulative trauma and trigger digits has not yet been firmly established. Most cases involve a single digit, some have multiple affected digits and patients with multiple affected digits at presentation are three times more likely to have a subsequent digit affected. Spontaneous recovery has been reported in 20% to 29% of cases of trigger finger.

Trigger finger occurs more commonly in patients with diabetes mellitus (probably due to glucose-induced collagen modifications), carpal tunnel syndrome, Dupuytren's disease, rheumatoid arthritis, amyloidosis, hypothyroidism, mucopolysaccharide storage disorders and congestive heart failure.

Currently available treatment modalities are operative (open or percutaneous surgical division of the A1 pulley) and non-operative (corticosteroid injections and splinting). Operative therapy is effective (60-97% cure-rate) but associated with higher cost, longer absence from work and the possibility of surgical complications. Corticosteroid injection seems to be as effective as surgical therapy with non-randomized studies reporting cure-rates ranging from 73-94%. In a comparative study splinting was effective in 70% of cases, compared with 82% receiving an injection. It is not clear through which mechanism of action local corticosteroids show their benefit. Common belief is that they act as an anti-inflammatory agent reducing the swelling at the A1 pulley and thus correcting the mismatch between tendon and sheath. The effects of corticosteroid injection seem to diminish after multiple injections, especially after the second injection. There have been no reports of serious complications of injection therapy, but possible side effects could be steroid flare, tendon-ruptures, local infection, allergic reactions to corticosteroids and atrophy of subcutaneous fat-tissue.
Since effectiveness of corticosteroid injections has never been assessed in a randomized double-blinded trial design and treatment provided by a primary care provider could be advantageous for the individual patient (because of shorter waiting times, the possibility of providing treatment in the proximity of the patient and fewer costs), we decided to conduct a randomized controlled trial in the setting of general practice.

Methods
This trial is part of a larger study called the Groningen Hand and Wrist Injection Therapy Trial (HAWITT) in which efficacy, safety and feasibility of steroid injections for carpal tunnel syndrome, de Quervain’s tenosynovitis and trigger finger in primary care is evaluated. In this report the results for trigger finger are described.

The trial was approved by the Medical Ethics Committee of University Medical Center Groningen (METc 2002/020c).

Setting
Patients were recruited from the practices of 21 general practitioners in the northern part of the Netherlands.

Patient recruitment and exclusion criteria
Patients presenting to the participating general practitioners with a clinical diagnosis of trigger finger were recruited in the period of 2003-2005. A clinical diagnosis of trigger finger was defined as a history of triggering or locking of a finger with or without pain and tenderness or swelling at the A1-pulley. Exclusion criteria were being of minor age (less than 18 years of age), presence of an absolute contraindication for corticosteroid injection, prior treatment in the last six months with steroid injection and/or surgery at the same anatomical location, possible traumatic or neoplastic origin of symptoms, inability to fill in follow-up forms or absence of self determination in the participating patient. After written informed consent was given and baseline data were collected, patients were randomized to either steroid or saline injection.

Randomization and allocation concealment
Randomization was done using an electronic online randomisation tool developed by G. Urbaniak (www.randomizer.org, accessed on 22.12.2002). Block randomisation was performed by creating 5 sets of blocks of 10 random numbers. Even numbers corresponded with active trial medication and uneven numbers with placebo to ensure equal numbers of allocation to active and placebo treatment. Treatment allocation was written on a paper and enclosed in an opaque and sealed envelope. After inclusion of a patient a pharmacy assistant who was not involved in the study drew an envelope and sent the allocated trial medication to the injecting general practitioner.

Study design, blinding and bail-out treatment
Every patient with a clinical diagnosis of trigger finger presenting to one of the participating general practitioners was asked to participate in the trial. After applying inclusion and exclusion criteria assessment of baseline clinical characteristics took place by the patient’s general practitioner, who also performed the blinded assessment of the short term follow-up (two weeks after the intervention) (table 1). In order to guarantee the blinding of the short term outcome assessment the trial medication
(after randomization) was sent to a second independent general practitioner, who injected the patient with the trial medication one week after inclusion. After injection the patient was instructed to return again to the second independent general practitioner one week later for a second injection if the result of the first injection was not satisfactory in the patient’s opinion. If the patient was satisfied with the result of the first injection, no further treatment was given and the patient was instructed to return after two weeks to his own general practitioner (for assessment of short term outcome) Because a placebo look-alike of the triamcinolonacetonide injection suspension could not be manufactured, patient blinding was realised by applying the injection therapy while the patient was blindfolded.

**Bail-out treatment**
If during short term outcome assessment the response to the blinded injection(s) was insufficient according to agreement between the patient and general practitioner blinding was discontinued and the trial centre was asked whether injected trial medication consisted the active substance (TCA) or placebo (NaCl). In case of insufficient response after injection of NaCl, 1-2 additional injections with TCA with weekly intervals were given without blinding for bail-out treatment.

Introducing bail-out treatment for non-responders to NaCl was required, as the medical ethics committee considered it to be unethical to leave patients, who received placebo treatment with no improvement in symptoms after intervention, untreated.

All patients were followed up for 12 months after short-term assessment.

**Injection technique**
All participating general practitioners and independent physicians were offered a two-hour course on the technique of injection therapy, using an arm/hand phantom for instruction. One millilitre of a solution of trial medication was deposed around the thickened part of the affected flexor tendon. Intra-sheath injection was not obligatory because this seems to be difficult and not important for the treatment response.

**Outcomes measurements**
During short term assessment primary outcome measurements were recorded.

direct treatment response (consensus between physician and patient):
- 0 = no response
- 1 = partial response, but not satisfactory, warranting further treatment
- 2 = partial response, satisfactory, not warranting further treatment
- 3 = complete resolution of symptoms and signs

perceived improvement (by patient)
- -2 = much worse
- -1 = worse
- 0 = not better/ not worse
- +1 = better
- +2 = much better

frequency of triggering:
- 0 = never
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1 = incidental
2 = weekly
3 = daily
4 = always

1. Pain and discomfort in the palm of the hand using a numerical rating scale: 0 = no pain; 10 = severe pain

2. Functional improvement was recorded by using the sub items hand and finger function of the Dutch version of the second version of the Arthritis Impact Measurement Scale (DUTCH AIMS-2), see appendix. Five questions are asked regarding impairment of hand and finger function, using a numerical rating scale from 1 to 5. The sum of the score for each question is the total AIMS-2 score. Higher total AIMS-2 scores correspond with more severe functional impairment.

The secondary outcomes of adverse events and patient satisfaction (measured with a numeric rating scale: 0=not satisfied, 6 very satisfied) were also monitored one week after the last injection and during the follow up phase.

Follow up measurements were performed by sending questionnaires to participating patients 1, 3, 6 and 12 months after the last injection and consisted of the same outcome measures as during short term assessment except for direct treatment response. In addition patient satisfaction was recorded.

Sample size and data analysis
Calculations of sample size were based on a two-sided alpha of 0.05, a statistical power of 0.90. The proportion of patients treated with steroid injection with satisfactory response or complete resolution of symptoms after two injections was expected to be at least 70 %, extrapolated from prior prospective studies. Adequate treatment response to placebo treatment was expected to be 20 %. Based on these calculations we aimed to recruit 25 patients for each treatment group. Analysis was done according the intention to treat principle. For continuous data the student T-test was used if the distribution was normal and Mann-Witney U test if there was not a normal distribution. For categorical data Fisher’s exact test was used. Friedmann’s test was used if a non-normal distribution of outcome data was suspected. Significance was accepted at a probability value of < 0.05. Data were analysed using the statistical software SPSS version 12 (SPSS Inc., Chicago, Illinois, USA).

Results

Baseline clinical characteristics
The two groups differed only in mean duration of symptoms. This was due to one outlier in the TCA-group with a very long history of symptoms (table 1).

Short-term efficacy
Table 2 shows the results of outcomes one week after the last injection as compared to baseline measurement. The TCA-group showed significant improvement in direct treatment response, severity of local pain, the perceived improvement and total scores of AIMS-2 sub items hand- and finger function. Also a trend towards in reduction of
frequency of triggering of the affected finger was found (27.3% improvement in the NaCl-group versus 54.2% improvement in the TCA-group, p=0.053). The Relative Risk Reduction was 0.38 (95% CI: -0.019, 0.684) with a Number Needed to Treat of 4 (95% CI: -72, 2).

Long-term efficacy
Since only five patients in the NaCl allocated group responded to treatment and the non-responders required subsequent “bail-out” injection with TCA it was decided to present the long term follow-up of twelve months as a cohort report of patients that had received treatment with TCA. Because the blinding of the non-responders in the NaCl group was discontinued the long-term outcomes of the NaCl-group that had received bail out TCA treatment and the original responders of the TCA-group were analyzed separately. In table 3 the proportion of patients without triggering of their finger, the proportion of patients who perceived recovery as better or much better (as compared to pre-intervention), the median of severity of local pain in the hand and the median of the total AIMS-score during the follow-up phase are displayed. It shows that the outcomes between the two groups during follow-up did not differ significantly. Also none of the outcomes changed significantly during the follow-up period. One patient was referred for operative treatment during the treatment phase, 4 patients received more injections during the follow-up phase (1 between 3 and 6 months post intervention and 4 between 6 and 12 months after the intervention; 4 of these patients were randomized to NaCl and 1 randomized to TCA).

41 of the 50 (82%) of the included patients completed the full follow-up period. 32 of the 41 (78%) patients receiving at least one injection of TCA (including blinded and bail-out treatment) completed the full follow-up and were analyzed for long term results. 13 patients could not be included in the analysis for long term effects because of protocol violations (4 patients did not receive bail-out injections) and lack of follow-up data (9 patients did not return the follow-up forms).

Complications of treatment
There were no serious adverse events such as tendon ruptures or deep skin infections. The most frequent reported minor side effects were hot flushes (9 patients) and steroid-flare (6 patients).

Patient satisfaction
The average treatment satisfaction was 3.97 (SD 2.26) measured with a numeric rating scale (0=not satisfied, 6 very satisfied).

Discussion
This is the first randomized placebo controlled trial assessing efficacy and safety of steroid injection for trigger finger. The data of our trial show that treatment with one to two injections of triamcinoloneacetonide (10 mg/ml) is more effective than placebo in adults after one week. The positive effect of one or two TCA injections remains during the follow-up period of 12 months. It results in reduction in frequency of triggering and pain, leads to functional improvement and is safe and associated with a high degree of patient satisfaction.
Studies evaluating possible treatments have so far been characterized by poor methodological quality (mostly non-randomized studies using not validated and heterogenic outcome measures). We used a rigorous randomization procedure with blinding of patient and outcome assessor. Also clearly defined and clinical relevant outcomes with validated outcome measures (when available) were used. Notably in our study the patient-group randomized to TCA-treatment had longer symptoms at baseline assessment, nevertheless all outcomes were better for this group.

Due to the decision of the ethical committee we had to discontinue the blinding if after 1-2 blind injections the treatment effect seemed to be insufficient. Because of this and the high proportion of non-responders in the NaCl-group, long-term effectiveness could only be properly assessed by analyzing the outcomes of the two groups of patients who had received TCA (as active treatment or as bail-out treatment, in case of non-response after NaCl injection). It appeared that the treatment effects of TCA were sustained during the follow-up period of 12 months equally in both groups. Since there are no reports available that describe the natural course of trigger finger it is not possible with the data from our study to make any statements about how steroid injection therapy compares to a wait and see strategy for the management of trigger finger.

Another shortcoming of our study could be that 13 of the 50 (26%) included patients could not be analyzed for long term effects due to protocol violations and lack of follow-up data. We think that the complicated study design could have been an important factor in this matter.

This study proves that injection therapy provided by a primary care provider is an effective and safe alternative to surgical therapy and we suggest that initial treatment for trigger finger should be injection therapy with 1-2 local injections with corticosteroids and in case of insufficient response or recurrence the patient should be referred for surgical treatment.

Conclusion

One or two local injections of 1 ml triamcinolonacetonide 10 mg/ml is an effective and safe method of treatment for trigger fingers compared to placebo injection. The initial beneficial effect of steroid injections lasts up to 12 months.

Acknowledgements and affiliations

The authors wish to thank all participating general practitioners and the employees of pharmacy “Apotheek Scheemda” for their contribution to this study.

Contributors: CPV is the guarantor and was responsible for daily project-management, trial-design, trial-logistics, data-collection and text of the paper and was supervised during these processes by JCW and BMJ. JCW initiated the study, obtained funding, contributed to the trial design and text of the paper. KHG performed the statistical analyses and BMJ contributed to the design of the trial and text of the paper.

Funding: This study was financially sponsored by the “Fund for Common Disorders” of the Dutch College of General Practitioners.
**Competing interests:** C. Peters-Veluthamaningal received an unrestricted educational grant by the pharmaceutical company Bristol-Myers Squibb. Bristol-Myers Squibb had no role in the organization of the trial and analysis or publication of data.

**Trial registration number:** ISRCTN53171398
Figures

Figure 1 flowchart: flow of patients
Tables

**Table 1 baseline characteristics of patients with trigger finger**

<table>
<thead>
<tr>
<th></th>
<th>TCA (n=25)</th>
<th>NaCl (n=25)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>male: female</td>
<td>10:15</td>
<td>12:13</td>
<td>0.4</td>
</tr>
<tr>
<td>mean age</td>
<td>63.3 (14.3)</td>
<td>63.0 (9.6)</td>
<td>1.0</td>
</tr>
<tr>
<td>mean duration of symptoms in weeks</td>
<td>24 (7.52)</td>
<td>7 (4.12)</td>
<td>0.023</td>
</tr>
<tr>
<td>affected hand (R : L)</td>
<td>13 : 11</td>
<td>13 : 11</td>
<td>1.0</td>
</tr>
<tr>
<td>affected finger (1/2/3/4/5)</td>
<td>3/0/6/2/2</td>
<td>8/1/5/6/2</td>
<td></td>
</tr>
<tr>
<td>dexterity (R:L)</td>
<td>19:4</td>
<td>23:2</td>
<td>0.35</td>
</tr>
<tr>
<td>prior history of TF (yes:no)</td>
<td>5 : 20</td>
<td>5 : 20</td>
<td>1</td>
</tr>
<tr>
<td>repeated movements of hands (yes:no)</td>
<td>16 : 8</td>
<td>20 : 5</td>
<td>0.52</td>
</tr>
<tr>
<td>median frequency of triggering (P_{25}, P_{75})</td>
<td>3 (3, 4)</td>
<td>3 (3, 4)</td>
<td>0.61</td>
</tr>
<tr>
<td>median severity of pain at affected digit (P_{25}, P_{75})</td>
<td>5 (4, 6)</td>
<td>4 (3.25, 6)</td>
<td>0.31</td>
</tr>
<tr>
<td>median AIMS total score (P_{25}, P_{75})</td>
<td>2.2 (1.4, 2.7)</td>
<td>1.8 (1.0, 2.3)</td>
<td>0.18</td>
</tr>
</tbody>
</table>

**Table 2 Short-term outcome in patients with trigger finger (one week after treatment with 1-2 injections)**

<table>
<thead>
<tr>
<th></th>
<th>TCA (n=25)</th>
<th>NaCl (n=25)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>direct treatment response (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no response</td>
<td>2 (8)</td>
<td>15 (60)</td>
<td></td>
</tr>
<tr>
<td>partial response, not satisfactory</td>
<td>7 (8)</td>
<td>5 (20)</td>
<td></td>
</tr>
<tr>
<td>partial satisfactory response,</td>
<td>7 (28)</td>
<td>5 (20)</td>
<td></td>
</tr>
<tr>
<td>complete resolution of symptoms</td>
<td>9(36)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>P&lt;0.0005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pts with improvement in frequency of triggering (%)</td>
<td>13/24 (54.2)</td>
<td>6/22 (27.3)</td>
<td>P=0.053</td>
</tr>
<tr>
<td>change in mean severity of pain</td>
<td>4.2</td>
<td>0.9</td>
<td>P&lt;0.0005</td>
</tr>
<tr>
<td>patient perceived improvement (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>much worse</td>
<td>1 (4)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>worse</td>
<td>0</td>
<td>3 (12)</td>
<td></td>
</tr>
<tr>
<td>not better/ not worse</td>
<td>2 (8)</td>
<td>13 (52)</td>
<td></td>
</tr>
<tr>
<td>better</td>
<td>9 (36)</td>
<td>8 (32)</td>
<td></td>
</tr>
<tr>
<td>much better</td>
<td>13 (52)</td>
<td>1 (4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>P&lt;0.0005</td>
<td></td>
<td></td>
</tr>
<tr>
<td>change in aims-2 total score (before and after intervention)</td>
<td>4.02</td>
<td>0.06</td>
<td>P=0.001</td>
</tr>
</tbody>
</table>
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Table 3. Results follow up from 1 month through 12 months for patients with trigger finger receiving one or more injections with TCA

<table>
<thead>
<tr>
<th>Follow up period</th>
<th>1 month</th>
<th>3 months</th>
<th>6 months</th>
<th>12 months</th>
<th>p-value³</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TCA</td>
<td>NaCl</td>
<td>TCA</td>
<td>NaCl</td>
<td>TCA</td>
</tr>
<tr>
<td>Frequency of triggering (% never)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Original study arm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TCA</td>
<td>70.6</td>
<td>57.1</td>
<td>66.7</td>
<td>50.0</td>
<td>55.6</td>
</tr>
<tr>
<td>NaCl</td>
<td>N=17</td>
<td>N=14</td>
<td>N=18</td>
<td>N=14</td>
<td>N=18</td>
</tr>
<tr>
<td>p-value⁴</td>
<td>0.121</td>
<td>0.486</td>
<td>0.767</td>
<td>1.000</td>
<td></td>
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<tr>
<td>Patient perceived recovery (% better or much better)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Original study arm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TCA</td>
<td>100.0</td>
<td>92.9</td>
<td>93.8</td>
<td>85.7</td>
<td>75.0</td>
</tr>
<tr>
<td>NaCl</td>
<td>N=17</td>
<td>N=14</td>
<td>N=16</td>
<td>N=14</td>
<td>N=16</td>
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<tr>
<td>p-value⁴</td>
<td>0.207</td>
<td>0.359</td>
<td>0.865</td>
<td>0.441</td>
<td></td>
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<tr>
<td>Median severity of local pain (P25, P75)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Original study arm</td>
<td></td>
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<tr>
<td>TCA</td>
<td>0.0</td>
<td>(0.0, 2.0)</td>
<td>0.0</td>
<td>(0.0, 1.0)</td>
<td>0.0</td>
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<tr>
<td>NaCl</td>
<td>N=15</td>
<td>N=14</td>
<td>N=16</td>
<td>N=14</td>
<td>N=16</td>
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<tr>
<td>p-value⁴</td>
<td>0.872</td>
<td>0.656</td>
<td>0.612</td>
<td>0.610</td>
<td></td>
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<tr>
<td>Median AIMS total score (P25, P75)</td>
<td></td>
<td></td>
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<tr>
<td>Original study arm</td>
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<tr>
<td>TCA</td>
<td>1.0</td>
<td>(1.0, 1.2)</td>
<td>1.0</td>
<td>(1.0, 1.3)</td>
<td>1.0</td>
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<td>NaCl</td>
<td>N=17</td>
<td>N=14</td>
<td>N=18</td>
<td>N=14</td>
<td>N=18</td>
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<tr>
<td>p-value⁴</td>
<td>0.916</td>
<td>0.770</td>
<td>0.598</td>
<td>0.531</td>
<td></td>
</tr>
</tbody>
</table>

¹ Friedman test (TCA and NaCl combined)
² Chi-square test for trend
³ Mann-Whitney U test
References

Appendix

Questionnaire Dutch AIMS-2 sub items hand- and finger function:

NB: cijfer omcirkelen (1= iedere dag, 2= de meeste dagen, 3= sommige dagen, 4= weinig dagen, 5= nooit):

-kunt u met de aangedane hand gemakkelijk met een pen of potlood schrijven? 1—2—3—4—5
-kunt u met de aangedane hand makkelijk de knopen van een hemd of blouse sluiten/ openen? 1—2—3—4—5
-kunt u met de aangedane hand gemakkelijk een sleutel in het slot omdraaien? 1—2—3—4—5
-kunt u met de aangedane hand gemakkelijk een knoop knopen of een stropdas strikken? 1—2—3—4—5
-kunt u met de aangedane hand gemakkelijk een nog niet geopende pot met draaidop openen? 1—2—3—4—5