

Groningen Hand and Wrist Injection Therapy Trial (HAWITT)

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 05/11/2010	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms C. Peters-Veluthamaningal

Contact details
University Medical Center Groningen
University of Groningen Department of General Practice
Antonius Deusinglaan 1
Groningen
Netherlands
9713 AV
+31 (0)50 3632963
r.peters@home.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR326

Study information

Scientific Title

Efficacy and safety of corticosteroid injections for trigger finger, de Quervains tenosynovitis and carpal tunnel syndrome in primary care: a randomised, controlled trial

Acronym

HAWITT

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from local medical ethics committee

Study design

Randomised, double blinded, placebo controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Tenosynovitis, carpal tunnel syndrome

Interventions

One to two local injections of 1 ml of triamcinolonacetonide (10 mg/ml) versus 1 ml of NaCl 0.9% (placebo) one week after inclusion.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Triamcinolonacetone

Primary outcome measure

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:
 - 4.1. TF/MdeQ: Arthritis Impact Measurement Scale 2 (AIMS 2), sub items hand-and finger function
 - 4.2. 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 measures

1. Occurrence of short and long-term 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.

Overall study start date

01/12/2002

Completion date

01/12/2006

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

120

Key exclusion criteria

1. Under 18 years
2. Absolute contraindication 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

Date of first enrolment

01/12/2002

Date of final enrolment

01/12/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

University Medical Center Groningen

Groningen

Netherlands

9713 AV

Sponsor information

Organisation

University Medical Centre Groningen (UMCG) (Netherlands)

Sponsor details

Department of General Practice

Hanzeplein 1

Groningen

Netherlands

9713 GZ

Sponsor type

Hospital/treatment centre

Website

<http://www.umcg.nl/azg/nl/>

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Research organisation

Funder Name

Bristol-Myers Squibb (Netherlands)

Alternative Name(s)

Bristol-Myers Squibb Company, BMS

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Fund for Common Disorders from the Netherlands College of General Practitioners (Fonds Alledaagse Ziekten van het Nederlands Huisartsen Genootschap) (Netherlands)

Funder Name

University Medical Centre Groningen (UMCG) (Netherlands) - Department of General Practice

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2008		Yes	No
Results article	results	27/10/2009		Yes	No
Results article	results	29/07/2010		Yes	No