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Groningen Hand and Wrist Injection Therapy Trial (HAWITT)

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
05/11/2010

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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)
Triamcinolonacetonide

Primary outcome(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex

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)

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Research organisation

Funder Name
Bristol-Myers Squibb (Netherlands)

Alternative Name(s)
Bristol-Myers Squibb Company, Bristol Myers Squibb, Bristol-Myers 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

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