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'Trigger finger': comparative analysis of treatment methods by steroid injection, percutaneous release and open surgery

Submission date
20/07/2010

Recruitment status
No longer recruiting

Registration date
04/10/2010

Overall study status
Completed

Last Edited
13/08/2014

Condition category
Musculoskeletal 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A comparative analysis of treatment methods, steroid injection, percutaneous release and open surgery for patients with stenosing tenosynovitis: a randomised controlled clinical trial

Study objectives
The 'trigger finger' is a case of stenosing tenosynovitis which occurs as a result of blocking the active extension of the fingers as a result of disproportion between the diameter of the flexor tendons and pulley system. This phenomenon occurs when the tendon has its landslide blocked the pass through the tunnel on the A1 pulley osteofibroses not getting more touring and naturally return to starting position. Its etiology is unknown. Causal factors which are cited include, the presence of cyst intratendineous, synovial proliferation and fibrosis of the flexor sheath, although no consensus as to its true cause.

Aims:
1. To compare the recovery rates of the 'trigger finger' by methods of corticosteroids injection, percutaneous release and conventional open surgery
2. Observe the rate of recurrence of the 'trigger finger' after the procedures
3. To analyse the complications associated with the methods used

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics in Research Committee of the Federal University of São Paulo, Hospital São Paulo, 23 /05/2003, ref: 0349/03

Study design
Single-centre interventional randomised active-controlled parallel-group clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Stenosing tenosynovitis (trigger finger)

Interventions
150 'trigger fingers' were randomised using sealed envelopes to one of three treatments:
1. Corticosteroids injection (n = 49): 2 ml methylprednisolone acetate 40 mg/ml injection at the site corresponding to A1 pulley, trying to inject the solution inside the tunnel osteofibroses
2. Percutaneous release (n=45): release of the A1 pulley, 40x12 with a needle through longitudinal movements, on the axis of the flexor tendon, introduced at the site corresponding to the A1 pulley
3. Conventional open surgery (n=56): skin incision 2 cm transverse to the axis of the finger, the palmar skin fold, followed by subcutaneous dissection and longitudinal opening of the A1 pulley

Results:
First injection showed a success rate of 57%. Patients whose trigger remained or relapsed underwent a second injection, increasing success rate to 86%. As for percutaneous release of trigger finger, trigger remission was obtained in all cases.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Trigger finger cure: Defined as the end the blockade of the finger and the free tour of its movement, maintaining remission of the 'trigger' for 6 months.
2. Recurrence of the trigger: Defined as the return of the finger blocking during the six month follow-up study
3. Failures:
3.1. Corticosteroid injection: Defined as trigger fingers that relapsed or continued blockade, after the second infiltration
3.2. Open and percutaneous release: Defined as trigger fingers that relapsed or maintained the blockade after treatment

Secondary outcome measures
1. Pain:
1.1. Local pain: Defined as pain reported at the site of the procedure in the thumb, index, middle, ring and little finger in the outpatient follow up visit (7 days, 14 days, 1 month, 2 months, 4 months and 6 months).
1.2. Joint pain: Defined as joint pain reported in the interphalangeal joint of the thumb and proximal interphalangeal of index, middle, ring and little finger at the outpatient follow up visit (7 days, 14 days, 1 month, 2 months, 4 months and 6 months).
2. Active motion of the fingers (Total Active Motion [TAM]): TAM is recommended by the Committee of tendon injuries of the International Federation of Societies for Surgery of the Hand (Kleinert, Verdan, 1983) to evaluate the active motion of fingers. To calculate the value of TAM, we add the degree of flexion of the three joints of the fingers in active flexion, subtracting the loss of extension, measured with the active finger extension. The measurements were performed with the goniometer on the dorsal region of the fingers. Measurements were taken before treatment and at 1, 2, 4 and 6 months post-treatment.

Overall study start date
01/11/2002

Completion date
03/03/2007

Eligibility

Key inclusion criteria
1. Patients of both sexes
2. More than 15 years with symptoms of blockage of the movement ('trigger finger') in any finger
3. No previous treatment for any type of therapy and classified as type II to IV in the classification proposed by Quinnell (1980)
4. Greater than 15 years of age, no upper age limit

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150 trigger fingers in 137 patients

Key exclusion criteria
1. Patients who refused to accept the consent approved by the Ethics in Research
2. Type I 'Trigger fingers'
3. Condition considered secondary to congenital partial tendon injury

Date of first enrolment
01/11/2002

Date of final enrolment
03/03/2007

Locations

Countries of recruitment
Brazil

Study participating centre
Rua Visconde De Inhaúma 81
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Sponsor information

Organisation
Federal University of Sao Paulo (Universidade Federal de São Paulo [UNIFESP]) (Brazil)

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Sponsor type
University/education

ROR
https://ror.org/02k5swt12

Funder(s)

Funder type
University/education

Funder Name
Federal University of Sao Paulo (Universidade Federal de São Paulo [UNIFESP]) (Brazil)

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	01/02/2014	Yes	No