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Clarification of the frequency, severity and duration of flare-up in symptoms in patients with joint and tendon-associated inflammation after treatment with ultrasound guided steroid injection-a prospective cohort study.

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INTRODUCTION:

It is well known that some patients experience flare-up symptoms as side effects after steroid injection, however the frequency, severity and duration of these symptoms are unclear (1;2). However, a minority of patients experience other side effects such as localized warmth, facial flushing and local skin depigmentation (1;2). We inform all patients about the possibility of side effects and flare-up symptoms due to steroid injection. The symptoms are not dangerous, but can be very debilitating. The post-injection flare-up in pain is the most commonly reported side effect.
In our clinic all injections are given using ultrasound guidance in order to ensure the steroid is placed in the inflamed structure. Evidence supports this praxis as improved effect of steroid injection therapy is seen when an ultrasound guided procedure is applied (3;4)
As all injections in our department are applied US guided it is very relevant; in order give the patient evidence based information of the risk and severity of the flare-up, to investigate this treatment procedure carefully.

Objective:

To register the frequency, severity and duration of side effects of steroid injection in musculoskeletal inflammatory conditions.

Hypothesis:

The distribution of the injected material in the inflamed tissue has an influence on the frequency, severity and duration of flare-up symptoms.

Definitions:

Flare-up symptoms=any worsening of the condition for which the patient is treated.
Side-effects=any new symptoms caused by the steroid injection.

METHODS:

Patients will be enrolled consecutively as they are assigned to steroid injection therapy owing to an inflammatory condition in joint, bursa and/or tendon tissues at the ultrasound unit at the Parker Institute, Department of Rheumatology, Frederiksberg Hospital. The enrolment will continue until 200 patients are included.

Enrolment

When the patients are assigned to a steroid injection they will be informed about the project and asked if they are willing to participate. If they will not participate, only the normal registration in relation to steroid therapy in the department will be made.

Injection:

The injection will be given using ultrasound guidance by a person experienced in this procedure (SPT, KE). An ultrasound clip (small film) of all injections will be stored in order to document if the steroid is placed in the joint cavity, bursa cavity, the tendon sheath or tendon and to assess the distribution of medicine in the inflamed structure.

Shoulder bursa, trochanter bursa, hip joint, knee joint: 1ml Depomedrol and 2 ml Lidocain

Wrist joint, Achilles tendon, patella tendon, metatarsal bursa: 1ml Depomedrol and 0.5 ml Lidocain

Mcp-joint, mtp-joint, tendon sheath: 1 ml Depomedrol

Ultrasound:

Furthermore, images of any synovial hypertrophy and Doppler activity will be stored for later documentation.

Before the injection therapy, patients will fill in an electronic VAS (visual analogue scale) for pain in both rest and activity in the inflamed region.

The patient will receive an appointment for a control visit in approximately 14 days.

Interview:

Two days after the injection therapy the patient will be contacted by telephone in order to register any side effects or flare-up due to injection therapy.

If any side effects are reported the patients are asked to indicate the severity of each of the symptoms on a scale from 0 to 10. If any pain flare-up is reported, the severity of the symptoms must be registered in both rest and activity.

Furthermore, the patient will be asked the following questions to characterize the severity of the symptoms.

1. Did you take any pain killers for pain due to the injection? YES/NO
2. Did flare-up symptoms disturb your sleep? YES/NO/Do not know
3. Did flare-up symptoms cause reduced function? YES/NO/Do not know
4. How long did the flare-up last?

Follow up visit:

At the follow up visit patients will fill in a VAS (visual analogue scale) for pain in both rest and activity in the inflamed region in order to register any change in symptoms after steroid therapy.

US evaluation

The US examinations will be evaluated by another person, than the one who performed the examination. The examination will be evaluated for the following conditions:

-Distribution of injection material in the inflamed tissue (local/in all tissue); the injected material runs freely away from the needle tip, the injected material runs away from the needle tip and the structure expands, the injected material expands around the needle tip.

-Doppler activity.

-Synovial hypertrophy.

A consensus in the evaluation between the two persons (KE and STP) evaluating the US examination will be made before starting of the project.

Inclusion criteria:

Age > 18 years

Patients with an inflammatory and painful condition in the joint, bursa, or tendon tissues assigned for US guided steroid injection therapy.

Exclusion criteria:

Any contraindications for steroid injection.

Variables:

Baseline registration (day of injection):

- VAS for pain in rest and activity in the inflamed structure
- US measured synovial hypertrophy and Doppler activity
- Distribution of injected medicine.

Registration of side effects (after two days):

1. Post injection pain (VAS)
2. Localized warmth (VAS)
3. Facial flushing (VAS)
4. Skin depigmentation (registration at follow-up visit)

Answer to questions about side effects (YES/NO/do not know)

Registration of treatment response (after approximately 14 days):

- Electronic VAS for pain in rest and activity in the treated structure
- US measures (synovialhypertrophy and Doppler activity)

Primary outcome:

Dichotomous registration of occurrence of any of the side effects and flare-up symptoms

Secondary outcomes:

A. Type and severity of the flare-up symptoms
B. Treatment response:
    - change in amount of synovial hypertrophy and Doppler activity
    - Change in VAS in rest and activity in the inflamed structure

All patients' exclusion from the study will be registered and reason for exclusion will be registered.

The results will be presented as the number of patients who experience flare-up symptoms. The mean average of the time and severity of the symptoms will be described.

The Committees on Health Research Ethics for the Capital Region of Denmark approved the study/registration (H-1-2013-FSP -76).

Publication

Results from the study will be sent to international peer-reviewed medical journals.

Reference List

(1) Gaujoux-Viala C, Dougados M, Gossec L. Efficacy and safety of steroid injections for shoulder and elbow tendonitis: a meta-analysis of randomised controlled trials Ann Rheum Dis 2009 Dec;68(12):1843-9.

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(3) Naredo E, Cabero F, Beneyto P, Cruz A, Mondejar B, Uson J, et al. A randomized comparative study of short term response to blind injection versus sonographic-guided injection of local corticosteroids in patients with painful shoulder. J Rheumatol 2004 Feb;31(2):308-14.

(4) Jones A, Regan M, Ledingham J, Pattrick M, Manhire A, Doherty M. Importance of placement of intra-articular steroid injections. BMJ 1993 Nov 20;307(6915):1329-30.