STING Covid-19

A national multicentre service evaluation of musculoskeletal STeroid Injections durinG the COVID-19 pandemic

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Lay Summary

There is concern over the safety of steroid injections during the Covid-19 pandemic. There has been concern in the medical community that injected steroid may worsen symptoms in patients who subsequently go on to develop the SARS-CoV-2 virus. This has led to a nationwide change in practice to reduce the number of steroid injections performed for musculoskeletal conditions [1-2].

As the SARS-CoV-2 virus prevalence starts to wane, professional bodies have looked to reintroduce steroid injections, questioning the theoretical risk posed. Steroid injection can improve function and reduce pain, allowing patients to return to work and improve independence with activities of daily living.

In order to provide clinical evidence on the topic, this audit aims to prospectively gather information on musculo-skeletal steroid injections undertaken during the Covid-19 recovery period, capturing patient background Covid-19 risk and prospectively following patients over the subsequent 6 weeks comparing Covid-19 outcomes with the population.

Background and Rationale

Steroid joint injections are a simple and quick treatment for relieving pain in various musculoskeletal conditions. They are recognised as effective for producing symptomatic relief, improving function and can in some cases eliminate the need for surgery.

During the Covid-19 pandemic the use of steroid injections has been reviewed with respect to the immunosuppressive nature of steroid and thus the potential risk of increased susceptibility to Covid-19 and severity.

Reduction of patient attendance at health care institutions and avoidance of face to face review has been adopted to reduce patients risk of acquiring SARS-CoV-2 viral infection[3].

Various national professional bodies have published guidance urging clinicians to undertake a cautious risk-benefit analysis on a case-by-case basis when considering steroid injection as a treatment option during the Covid-19 pandemic [4-7]. Risk related to steroid injection was predominantly based on a study detailing observations of the effect of their use during previous Severe Acute Respiratory Syndrome and influenza epidemics. One retrospective study found, on multivariate analysis, that steroid injection was the most important predictive factor for contracting influenza. The study compared vaccinated control patients, vaccinated patients who also had at least one CSI, and unvaccinated patients who received at least one CSI over a period of 5 years. An absolute increase in annual influenza infection risk of only around one in 1,000 was found [8]. The timeline of events was not reported (injection, immunization, and infection), raising concerns when interpreting the relevance of the observed differences between the study groups [3]. Effect of steroid injection on endogenous cortisol pathways is reported to be maximal after 48 hours and to last for one to four weeks [9]. We should add in the dexamethasone work to show there is a body of evidence suggesting steroid may be beneficial

The aim of this study is to contribute to the evidence regarding the safety of local steroid injection by prospectively collecting data on SARS-CoV-2 viral contraction and severity post injection. Further it will aid clinicians to comply with specialist society advice on regulation and documentation of local steroid injection during Covid-19

Aims and Objectives

Aim:

To assess the number of patients who have a local steroid injection for a musculoskeletal pathology who develop SARS-CoV-2 virus infection.

Secondary Aims:

To aid clinicians to comply to guidelines on regulation and documentation of local steroid use during the Covid-19 pandemic

To compare practice in musculo-skeletal injections across specialties

To assess local complication rate after steroid joint injection

To assess patient reported effect on symptoms after steroid joint injection

To collate local guidelines on steroid joint injection practice

To access the impact of Covid-19 on the change to the service and protocols involved in musculo-skeletal steroid injections

Methodology

This is a national audit of steroid joint injection outcomes. Patient demographics related to baseline disease severity risk for contracting SARS-CoV-2 virus will be collected. Post injection outcomes from both the steroid injection and outcomes related to subsequent development of SARS-CoV-2 virus including morbidity and mortality relating to the virus will be collected. In the current situation, without knowledge of normal population SARS-CoV-2 rates a statistical comparison will not be possible. For the same reasons, calculating a sample size is not currently possible, nonetheless in prospectively collecting data we will be able to contribute to the knowledge on steroid safety as the pandemic progresses.

The variation in practice across specialities and localities as well as variation to practice since Covid-19 will be recorded. Patient reported outcome and local complication rates will also be recorded.

The time period will be from March 2020 until Sep 2020, with the flexibility to extend collection depending on analysis of initial data. Retrospective data collection is expected to include the initial COVID 19 pandemic period.

Setting

Any primary or secondary health care setting within the United Kingdom which offers steroid injection as a modality of treatment for a musculoskeletal problem, i.e. joint pathology, soft tissue conditions or nerve compression.

Participants

Any adult (aged 18 or over) undergoing a steroid injection as treatment for a musculoskeletal problem, i.e.joint pathology, soft tissue condition or nerve compression.

Inclusion Criteria

Adults (patients 18 years and over) who have steroid injection to treat a musculoskeletal problem, i.e.joint pathology, soft tissue condition or nerve compression

Exclusion criteria

None

Variables

Data to be collected: age at time of injection, gender, weight, height, ethnicity, smoking status, major comorbidities, frailty index, site of injection, indication, type concentration and volume of steroid injected and local anaesthetic or imaging techniques were used, and any peri-injection self-isolation including duration.
Data collected at follow-up: adverse events early, e.g. infection, patient reported outcome on symptoms, any post-injection self-isolation including duration. Symptoms, diagnosis and treatment related to Covid-19.

Data collection method: anonymised recorded on an electronic database inputted by the treating clinician with follow-up and further input by the treating clinician.
Please see the appendix for the data dictionary.

Data management and storage

Study data will be collected and managed using REDCap electronic data capture tools hosted at the Kennedy Institute of Rheumatology and the University of Oxford. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing:
1) an intuitive interface for validated data entry
2) audit trails for tracking data manipulation and export procedures
3) automated export procedures for seamless data downloads to common statistical packages
4) procedures for importing data from external sources.

More information about the consortium and system security can be found at http://www.projectredcap.org/. Data collection and management will adhere to Caldicott II principles and GDPR. No patient identifiable data will be collected. Data for each patient will be pseudo-anonymised using a unique alphanumeric number that will be held securely by the local site.

Ethics and Governance

This is a prospective service evaluation which will be undertaken without interference with the decision making process regarding whether or not to perform steroid injection. Ethics approval was not required. This was confirmed using the HRA decision tool. Patients do not need to provide written consent for their data to be included in this study, provided that their usual care is unchanged and collected data is completely anonymised.

Declaration of Helsinki

The Chief Investigator will ensure that this study is conducted in accordance with the principles of the principles of the declaration of Helsinki

Guidelines for good clinical practice

The Chief Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

Participant confidentiality

The participants' anonymity will be maintained. Clinician responses will be anonymous. Participants will have identifiable details stored securely at the local site. These will be matched with a unique REDCap ID. The study will comply with the Data Protection Act and General Data Protection Regulation 2016/679.

Dissemination

The final report will be prepared in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines. The publication will have 3 levels of authorship. Chief Investigator decisions on collaborator status are final.

Named authors

Named authors will need to meet the International Committee of Medical Journal Editors (ICMJE) criteria (www.icmje.org) based on the following four criteria:

1. Substantial contribution to the conception or design of the work; or the acquisition, analysis or interpretation of the data for the work and
2. Drafting the work or revising it critically for important intellectual content and
3. Final approval of the version to be published and
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Citable collaborators

- A collaborator certificate outlining their contribution to the study.
- Acknowledgement on any presentations relating to the study.
- Local data set.

Acknowledged collaborators

Acknowledged contributors will include consultant surgeons who supported the project and other contributors who provided data but did not reach the threshold for citation. A minimum threshold will be 20 set. Acknowledged contributors will receive a certificate of participation and acknowledgement in the manuscript.

References

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