Primary Investigator: Michael B. Furman, MD
Co-Investigators: Jeffrey R. Conly, MD, Jason G. Anderson, DO, Tejas N. Parikh, MD
Research Design: Prospective, non-randomized, observational human study.

Purpose: To assess functional outcomes after fluoroscopically guided interlaminar epidural steroid injections

Background:
Cervical Interlaminar steroid injections are an accepted treatment in the comprehensive, conservative care for neck pain with a radicular component secondary to cervical disc pathology. Although there are no controlled randomized studies evaluating the effectiveness of cervical epidural steroid injections, prospective studies have shown significant reduction in extremity pain following transforaminal and interlaminar injection[1, 4, 5]. Observational studies of cervical transforaminal injections have suggested that some 30% of patients can obtain partial, but lasting, relief of their pain, and a further 30% can obtain complete relief[6-8]. Similar trends have been reported with cervical interlaminar epidural injections[9, 10]. However, these were performed without fluoroscopic guidance and have limited outcomes investigated. This study will specifically investigate the functional outcome following cervical interlaminar epidural steroid injection, performed under fluoroscopic guidance (contrast enhanced), and will utilize a full battery of outcome measures. This is a pilot study funded by the International Spinal Intervention Society (ISIS).

Inclusion/Exclusion Criteria:
Patients who are undergoing cervical interlaminar epidural steroid injections at our outpatient interventional spine practice will be recruited for the study. Inclusion criteria are those already used in our clinic for ESIs. Patients with cervical radicular pain as defined by the following characteristics will be enrolled: 1. Shooting or lancinating pain radiating into the upper limb; 2. Pain precipitated or aggravated by root tension tests (such as Spurling’s or the axial compression test), and/or evidence on MRI of a disc herniation that compromises an adjacent spinal nerve or its root; 3. Pain in the upper limb worse than pain in the neck. Exclusion criteria include:

1. Any irreversible psychological barriers to recovery (e.g. drug addiction, or depression not due to persistent neck pain)
2. Any anatomical anomalies that might interfere with the safe conduct of the procedure.
3. Any illness or disorder that interferes with the safe conduct of the procedure. These might include: allergy to local anesthetics, antibiotics, or radiographic dyes; a tendency to bleed; or an inability to lie still, e.g. because of persistent cough;
4. Pregnancy;
5. Inability to provide the information necessary to assess the outcome of the treatment.
6. Concomitant painful condition, such as rotator cuff injury, that might interfere with the patient’s ability to determine the degree of relief of their radicular pain.
7. Conditions, such as spinal stenosis or spondylolisthesis greater than grade 2, which might constitute alternative causes of radicular pain and which are not known to be responsive to treatment with ESIs.
8. Previous treatment with ESIs at inception.
9. Litigation
10. Worker’s compensation
11. Age younger than 18 years-old
12. Self-reported 3 day average pain score less than 5/10 at inception.
13. Previous surgery in the cervical spine.
14. Radicular upper limb pain that is less painful than axial neck pain.

Additionally, patients will be dropped from the study after being enrolled if an exclusion criteria
condition occurs during the course of their participation in the study or they elect to have surgery or a
different type of injection (transforaminal epidural steroid injection, medial branch blocks, etc.). They
will also be dropped from further participation in the study if they have a major surgery, suffer a major
trauma (such as sustained in a motor vehicle accident), or are diagnosed with a new major medical
condition (such as metastatic cancer) during the course of their participation in the study that would
possibly cause new radicular or non-radicular pain.

Patient Enrollment:
Those fulfilling the above inclusion and exclusion criteria will be presented the option of participation.
The participants then will be presented the research consent form, in addition to our standard consent
form (attachment 1). The interventionist (MBF, JJJ, DMG, MAK) will determine the appropriate level
to inject according to both the patient’s clinical scenario and radiographic imaging data, using our
typical technique for cervical interlaminar epidural steroid injection. Estimated number of patients to
be enrolled is 50. Patients will be paid $25 to compensate for transportation and time to fill out the
paper work for the initial baseline data and each subsequent study-related follow-up visit.

Repeat Treatment:
If an enrolled patient experiences satisfying relief from their initial treatment, but that relief wanes, the
patient may elect to have that treatment repeated within a 12 month period following the initial
treatment or follow-up injection. If a patient elects to have their treatment repeated, they will resume
assessment as if the repeat treatment constituted their first treatment. However, they will be recorded
as having a repeat treatment, and records will be maintained of each period of response after each
treatment. Up to a total of three treatments (inception treatment and two follow-up treatments) will be
allowed. If, after 3 treatments, the patient’s response wanes, they may elect to pursue an escape
treatment (surgical consultation or a different type of injection).

Research Procedures:
All procedures will be performed in our procedure suite under fluoroscopic guidance with contrast
enhancement by one of the attendings in the practice (MBF, JJJ, DMG, MAK). The patients will be
prepped and draped in a sterile fashion in the prone position for the procedure. The assistance of a
registered nurse will be utilized as necessary, to obtain intravenous access, provide optional sedation,
and monitor appropriate vital signs and pulse oximetry as per our usual protocol.

We will utilize our standard cervical interlaminar epidural steroid injection protocol for all study ESI’s,
which is as follows: The fluoroscope will be positioned so that an anteroposterior (AP) view of the
appropriate interlaminar space is visualized. The overlying soft tissue will be then anesthetized with
1% Lidocaine without epinephrine. An appropriate length epidural needle will be inserted into the
epidural space using the paramedian approach. Under biplanar visualization, the needle will be
advanced into the epidural space. Epidural placement will be confirmed with "loss of resistance" and
contrast injection confirmed in two planes. Then, a solution containing 2cc of Betamethasone
(6mg/ml) and 2cc of normal saline will be injected into the epidural space.

The research technique described above is our typical treatment technique.

Data to be collected include the following outcome measures, which will be collected pre-procedure,
and post-procedure at 2 weeks, 6 weeks, 3 months, 6 months, 9 months, and 12 months:

Numeric Pain Rating Scale (NPRS)
SF-36 Health Survey
Neck Disability Index (NDI)

Assessment of Quality of Life Instrument (AQOL)

Work history

Analgesic use log,

Ancillary treatment log

Reports of overall degree of pain relief or lack thereof on an 8-point LIKERT scale

How many of their four patient-specific ADLs are partially or completely restored.

They will be asked if they would repeat the treatment for the results obtained.

Other data collected at inception, include the following epidemiologic data:

Gender, age, date of birth, diagnosis (neck pain with radiation in upper extremities and level of cervical disc injury), level of injection, use of prescription pain medications and medical aid, level of assistance needed in daily life, social relationships, physical senses, communication with others, psychological well-being, duration of symptoms, and occupational status.

Data analysis will be conducted.

Risks/Benefits:

Risks: Potential risks of the injection include infection, bleeding, bruising, allergic reaction to the medications or contrast dye, renal (kidney) damage, nerve damage, paralysis, epidural hematoma, headache, syncope, scar, increased pain 1-3 days after the procedure, respiratory/cardiac (heart) arrest and if diabetic, increased blood sugar level(s). Serious allergic reactions can be life threatening. The patient’s condition and symptoms may not get better, or may become worse during the study. There may be side effects to the treatment that are unknown at this time. These are the usual risks associated with epidural injections. There are no increased risks by participating in the research protocol.

Benefits: The goals of the procedure are to improve neck and shoulder/arm pain, and improve patients' function without the need for surgery. Participation in this study may benefit patients having epidural steroid injections in the future by contributing to our understanding of patients' outcomes after cervical epidural injection.

Should the results of this pilot study show reasonable functional benefits, a more rigorous follow-up study will be planned (i.e. double blind rCT).

Intended Use of the Results:

Depending on our findings, we may recommend this treatment to improve quality of life outcome for people suffering from neck pain with radicular symptoms radiating to the upper limb(s).

References: