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PATIENT EDUCATION

SPINAL CORD STIMULATION

- WHAT TO EXPECT FROM A DORSAL ROOT GANGLION (DRG)/SPINAL CORD STIMULATOR (SCS) TRIAL?
- WHAT TO EXPECT FROM A DORSAL ROOT GANGLION (DRG)/SPINAL CORD STIMULATOR (SCS)
 PERMANENT IMPLANT?



WHAT TO EXPECT FROM A DORSAL ROOT GANGLION (DRG)/SPINAL CORD STIMULATOR (SCS) TRIAL?

The trial is a safe, reversible, and minimally invasive procedure completed in an out-patient procedure suite under sedation. It allows you to experience the DRG/SCS system for 3-5 days to determine how well it controls your pain. The trial involves a brief procedure (typically 15-30 minutes for SCS and 1-2 hours for DRG) in which you are initially sedated and later are woken up to give feedback. Using techniques similar to an epidural injection, the procedure includes the following steps:

BEFORE THE TRIAL

- 1. You will have a scheduled appointment with a Provider
- 2. They will meet you in clinic and conduct at least one session on:
 - a. Pain assessment
 - b. Pain distribution
 - c. Education as to how the trial will occur
 - d. Familiarization with the equipment which will be used as part of the trial
 - e. Discussion on how the success of the trial will be measured
 - f. Answer any questions regarding the technical aspects of the trial
- 3. You will then have an appointment with the Pain Specialist to
 - a. Discuss any further questions regarding the trial
 - b. Obtain informed consent regarding the trial
 - c. Book in a date for the trial.

ON THE DAY OF BOOKING PROCEDURE, PLEASE ADVISE STAFF IF YOU ARE -

- Taking blood thinners (especially warfarin and clopidogrel)
- Have an active Infection or don't feel well
- Diabetion
- Pregnant, or any chance of being pregnant
- Allergic to:
 - o Steroids
 - o Local anesthetics
 - o lodine
 - o Shellfish
 - o Betadine
 - o Chlorhexidine

THE DAY OF THE TRIAL

- PLEASE TAKE all your normal medications with a SMALL amount of water (except blood thinner medications
 which should have been discussed and stopped several days prior to the trial)
- DO NOT eat or drink (for 6 hours before your procedure, clear liquids 2 hours before)
- After arriving you will need to complete the necessary paperwork
- · You will then change into a hospital gown
- An Innovative Pain and Wellness physician, the Anesthetist, and the Spinal Cord Stimulator Representative will see you. They will answer any questions you may have prior to the trial.



IN THE PROCEDURE ROOM

- 1. A small IV will be inserted into one of your veins.
- 2. You will be given mild/moderate sedation, to allow the next few steps to be completed without any movement. Your heart rate and blood pressure will be monitored throughout the procedure.
- 3. Your skin is prepared with alcoholic chlorhexidine solution to sterilize the skin and you are given intravenous (IV) antibiotics.
- 4. Local anesthetic will be injected into the area where the needles will be placed into the back.
- 5. The needles are inserted through the skin into the Epidural space (the layer just outside the spinal cord) under X-Ray guidance.
- 6. Small leads are then inserted through the needles and positioned at the correct levels under X-Ray guidance.
- 7. You are then woken up and the leads are tested to check they are in the correct position. This involves you communicating with the staff as to whether you can feel any stimulation in the same area you normally feel your pain.
- 8. The leads may need to be moved while you are awake. This may cause some mild to moderate discomfort.

 Once the correct position of the leads has been confirmed you are once again sedated and the rest of the procedure is completed.
- 9. This involves removal of the needles and securing the leads position dressings.
- 10. You are then taken to recovery to wake up slowly.
- 11. Once you are discharged from recovery area, an Innovative Pain and Wellness physician will see you as well as the Spinal Cord Stimulator Representative, who will program the system and review you.

AFTER DISCHARGE, TO THE END OF THE TRIAL

- 1. You will be discharged home the same day as the procedure.
- 2. Please take all your normal pain medications so we can evaluate the effectiveness of the trial without any other changes in your treatment.
- 3. If you are taking blood thinners, please follow the instructions given to you by your cardiologist and/or the provider who is prescribing these medications for you.
- 4. You will be under regular review by:
 - a. Your doctor to see if there are any procedural complications such as infection, and for dressing changes if necessary.
 - b. The Representative from Abbott for program review and monitoring of efficacy of the device at reducing the pain
- 5. At the end of the trial your leads will be removed in the clinic as part of the Post Trial Assessment
- 6. The Post Trial Assessment is a meeting that usually involves the patient and their family, your doctor and Spinal Cord Stimulator Representative.
- 7. Usually the decision as to the success of the trial is discussed and if successful a plan for future implantation is finalized.

 Occasionally, a subsequent meeting may be arranged to give patients more time for reflection, as to the benefit of the trial and consideration regarding future implantation.



THIS PROCEDURE IS VERY SAFE AND USUALLY UNEVENTFUL. HOWEVER, AS WITH ANY PROCEDURE THERE IS ALWAYS SOME POTENTIAL RISKS.

MINOR COMPLICATIONS

- Continuing pain (no relief)
- · Minor bleeding in the area where the leads were inserted
- · Bruising in the area where the leads were inserted
- Temporary weakness or numbness from the local anesthetic or leads inserted
- Brief increased pain that may fluctuate in intensity
- · Skin irritation or numbness

MORE SERIOUS SIDE EFFECTS

- Infection at the lead insertion site or in the epidural space where the leads are positioned
- Permanent nerve injury including, weakness, numbness and neuropathic pain
- · Allergy to the anesthetic or antibiotic
- Worsening of any pre-existing medical dysfunction, such as cardiac, due to the anesthetic.
- Bruising around the area from needle trauma

Please discuss with your doctor any other questions you may have about this procedure or this information sheet. If you agree to have the procedure, you will be asked to sign a consent form.



WHAT TO EXPECT FROM A DORSAL ROOT GANGLION (DRG)/SPINAL CORD STIMULATOR (SCS) PERMANENT IMPLANT?

It has been determined that you are a candidate for permanent implantation of a Spinal Cord Stimulation device based upon the success of your trial. Your doctor will be performing the permanent implantation of the pain-relieving device with the assistant of another provider. There will also be an Anesthetist as well as a Representative from the Spinal Cord Stimulation company present.

ON THE DAY OF BOOKING PROCEDURE, PLEASE ADVISE STAFF IF YOU ARE -

- Taking blood thinners (especially warfarin and clopidogrel)
- Have an active Infection or don't feel well
- Diabetic
- Pregnant, or any chance of being pregnant
- Allergic to:
 - o Steroids
 - o Local anesthetics
 - o lodine
 - o Shellfish
 - o Betadine
 - o Chlorhexidine



WHEN YOU SCHEDULE THE PROCEDURE, PLEASE OBTAIN A PRESCRIPTION FOR MUPIROCIN - TAKE AS DIRECTED FOR 5 DAYS PRIOR TO THE IMPLANT

THE DAY BEFORE THE IMPLANT

- Please take a Hibiclens Bath the night before the Implant (Hibiclens can be purchased at Walgreens, Walmart, etc)
- . Change and sleep in clean sheets the night before the Implant
- Take another Hibiclens bath the day of the Implant

THE DAY OF THE IMPLANT

- PLEASE TAKE all your normal medications with a SMALL amount of water (except blood thinner medications
 which should have been discussed and stopped several days prior to the implant)
- DO NOT eat or drink (for 6 hours before your procedure, clear liquids 2 hours before),
- After arriving you will need to complete the necessary paperwork
- · You will then change into a hospital gown
- Your Doctor, the Anesthetist, and the Spinal Cord Stimulator Representative will see you. They will answer any
 questions you may have prior to the implant.

IN THE PROCEDURE ROOM

- 1. A small IV will be inserted into one of your veins.
- 2. You will be given mild/moderate sedation, to allow the next few steps to be completed as comfortably and safely as possible.
- 3. Your heart rate and blood pressure will be monitored throughout the procedure
- 4. Your skin is prepared with alcoholic chlorhexidine solution to sterilize the skin and you are given intravenous (IV) antibiotics
- 5. Local anesthetic will be injected to numb the area where the needles will be placed into the back
- 6. The needles are inserted through the skin into the Epidural space (the layer just outside the spinal cord) under X-Ray video.
- 7. Small leads are then inserted through the needles and positioned at the correct levels under X-Ray.
- 8. You are then woken up and the leads are tested to check they are in the correct position. This involves you communicating with the staff as to whether you can feel any stimulation in the same area you normally feel your pain.
- The leads may need to be adjusted but will only be done the minimal amount required to obtain optimal relief in an effort to minimize any discomfort.
- 10. Once the correct position of the leads has been confirmed you are once again sedated and the rest of the procedure is completed.
- 11. This involves removal of the needles and securing the leads position dressings.
- 12. You are then taken to recovery to wake up slowly
- 13. Once you are discharged from recovery area, your doctor will see you as well as the Spinal Cord Stimulator Representative, who will program the system and ensure you are comfortable to manage your programmer.

DISCHARGE INSTRUCTIONS

- 1. You will be discharged home the same day as the procedure.
- 2. You should have a follow-up appointment 3-5 days after the procedure for a wound check.
- 3. If your permanent Implant is traditional Spinal Cord Stimulator, the device will be programmed by a Spinal Cord Stimulator Representative the day of the implant. You and/or a family member will be notified should this not occur.
- 4. If your permanent implant is a Dorsal Root Ganglion Stimulator, the device will typically be turned on at your first follow-up appointment, which is 3-5 days post-op. You and/or a family member will be notified should this not occur.
- 5. Please take all your normal medications as well as any additional post-op pain medications/antibiotics as prescribed. Antibiotics may not always be prescribed- it is patient dependent.
- 6. You may resume your Blood Thinner medication the day of the procedure.
- 7. DO NOT shower until after your first follow-up appointment if it is determined that a shower is warranted based upon the status of your wound. It is OK to sponge bath, but DO NOT let the dressing get wet.
- 8. We recommend daily dressing changes after your first wound check appointment (or, as directed by the provider) until there is no drainage. Please contact the office if there is persistent drainage.
- 9. There will be steri-strips along your incision(s). Do not remove these. Once you can shower, they will fall off on their own. It is not abnormal for this to take up to 4 weeks to happen.
- 10. If there are sutures/staples present, they will be removed by a provider in the clinic 10-14 days after. Please make a follow-up appointment accordingly.
- 11. DO NOT submerge your wound in a bath, pool, etc. until your incision (s) is a clean, pink scar, which typically takes 4-6 weeks post-op.

MINOR COMPLICATIONS

- Continuing pain (no relief)
- Minor bleeding in the area where the leads were inserted
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MORE SERIOUS SIDE EFFECTS

- Infection at the lead insertion site or in the epidural space where the leads are positioned
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- Worsening of any pre-existing medical dysfunction, such as cardiac, due to the anesthetic.
- · Bruising around the area from needle trauma