



EVOLVE

RESTORATIVE CENTER

Intrathecal Drug Delivery Trial (IT Trial)

General Information

Your healthcare provider has determined intrathecal drug delivery may be helpful in treating your chronic pain condition. Intrathecal Drug Delivery is a method of delivering pain relieving medications into the intrathecal (or spinal space). This allows for a more potent delivery, with the intent of improving pain and reducing side effects. As can be appreciated, the intrathecal device is a platform, it does not define what medication is delivered continuously. The goal of the trial is to determine if and which medicine would be helpful. The trial, which is a single injection, is performed twice to reduce the chance of placebo interference and to improve the likelihood of this therapy providing long-term relief. The trial procedure is done in a surgery center. Once the injection is performed, the purpose of the trial is to try and answer a few questions:

- Do you feel improvement in your pain?
- Are you experiencing any side effects?

The duration of the stay in the surgery center can be from 4-8 hours, or extended overnight, based on the medication trialed. Once the trial is over, you and your health care provider will discuss the next steps in your pain care plan.

Intrathecal therapy has been used to treat a variety of disorders, including:

- Back pain
- Leg pain/Sciatica
- Neck pain
- Arm pain (radiating from the neck)
- Spinal Stenosis
- Herpes Zoster/Post herpetic Neuralgia
- Disc pain
- Abdominal and pelvic pain
- Face pain
- Headache
- Ischemic pain
- Angina
- Phantom limb pain

Procedure Information: What to Expect

Prior to the injection appointment, there may be some medications that need to be stopped and your health care provider will discuss these with you. They could include blood-thinning medications like anti-inflammatory medications (aspirin, Xarelto, Coumadin, and Plavix). You may also undergo blood and urine testing to test for infections prior to proceeding.

The procedure is performed in a surgery center. After arrival and check in, you are brought to the pre-operative area where you may be placed in a gown. Then, you will be escorted to the procedure room. You will lay on your stomach (facing down) with your back or neck exposed. An X-ray/fluoroscope is used to see the bones to guide needle placement. After a cold, cleaning solution is placed on our skin, it is important not to touch the area. You will then feel a pinch and a burn (much like a bee sting), which is the local anesthetic (numbing medicine). After that, you will feel a pressure and a poke. Once the intrathecal space is accessed, the medication is injected. A sterile dressing is placed, and you are then escorted to the post-operative area and then for potential subsequent discharged to home (depending on the medicine injected).

Information from You

You will be asked to complete a Pain Journal, after the injection, to track the pain relief you experienced after the diagnostic phase of the injection, typically within the first 1-12 hours. This is performed to keep track of your progress in real time, to ensure accurate information.

Post-Procedure Instructions

Typical things to expect may include:

- Some soreness around the injection site
 - Ice may be applied, keeping the area dry
- Resume medications as instructed by your provider. You will need to continue to stop your blood thinning medications throughout the trial.
- Avoid taking any opioid pain medications or sedating medicines for the next 24 hours
- No activity restrictions are necessary
- It is encouraged that you are active and attempt to do the activities that are typically hurtful.
- Keep ALL post-operative appointments
- Test drive the therapy to determine if it is right for you.

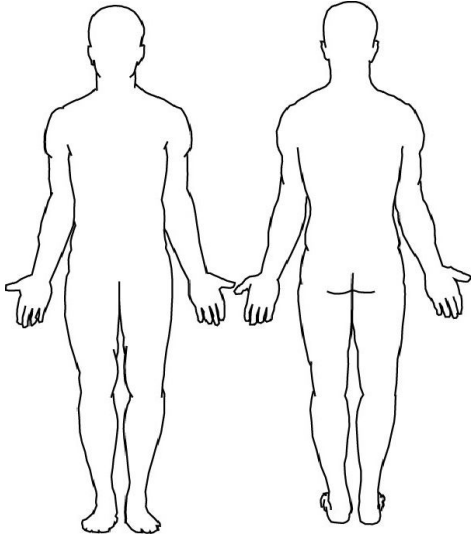
Things to Look-out for

Please contact our office (844) 527-7369 if you experience:

- Weakness in the arms or legs
- Redness or swelling around injection site for more than 24 hours
- Bladder or bowel accidents and/or numbness around the groin
- Any new areas of pain
- Fever or chills
- Any questions

Post Procedure Pain Diary

Please document where you are having your pain, intended for treatment, on the diagram, prior to the injection by shading in the below figure. Afterwards, please apply an X mark (X) on the intensity level of your pain, corresponding the appropriate time interval after the injection. Please bring this back to your follow-up appointment.



	Pain Scale	Before Injection (Baseline)	30 min (after injection)	1 hr (after injection)	2 hr (after injection)	3hr (after injection)	4hr (after injection)	12 hr (after injection)
Worst pain	10							
	9							
	8							
	7							
	6							
	5							
	4							
	3							
	2							
No pain	1							
	0							