



SPINAL (INTRATHECAL) DRUG PUMP TRIAL AND IMPLANT

Many patients with chronic pain are prescribed strong morphine-like drugs to control their pain and continue to take these successfully for many years, but often patients find that these drugs only take the edge off their pain and/or cause troublesome side-effects that are difficult to tolerate. Spinal morphine and similar drugs or baclofen work to relieve pain or spasticity by interfering with spinal cord messaging.

A trial of intrathecal drug therapy and implantation of a drug pump may be considered for some people when conventional treatment is unsuccessful or causes unmanageable adverse effects. The best way to test the ability of these drugs will be helpful is to do a series of test injections with active and inactive medicines.

RISKS:

Common to all therapeutic and diagnostic procedures there is the chance blood clots in veins and lungs, allergic reactions, haemorrhage/bleeding and death. The following problems may occur: inadequate or no pain relief, worse pain, postural head ache and medication side-effects. Rare problems include nerve damage, paralysis, loss of bladder / bowel / sexual function, equipment problems, meningitis or local infection that may require system revision or removal. Tolerance may develop and require alternate drugs or a 'drug holiday' to re-establish pain control/relaxation. Life threatening problems can arise from too much medication causing an over dose or sudden cessation by missing a refill causing withdrawals.

PREPARATION:

Please read the information provided, watch the DVD, be aware of the benefits, limitations and risks of the procedure and that any questions have been answered to your satisfaction. More information is available from the Medtronic website (see useful links) and <http://www.fpmx.com.au/solutions.html#treatment-procedures>

Please have your teeth checked by a dentist and any necessary work done BEFORE your surgery.

Ladies if you may be pregnant, please tell your doctor ASAP.

Please have nothing to eat for 6 hours and nothing to drink for 2 hours before any procedure.

Please take your normal medications with a sip of water.

Please obtain specific instructions, if you are taking strong analgesics, warfarin, clopidogrel, insulin or diabetic tablets.

PROCEDURE:

You may or may not undergo a trial of the therapy with "active" and "placebo" medications before receiving a permanent implant. Testing will vary with your condition and situation but may include one of the following methods:

1. One to four spinal injections of medication with an overnight hospital stay.
2. The insertion of a temporary spinal catheter and trial of several medications over a one-week hospital stay. If the trial is unsuccessful, the catheter is pulled out.
3. The implantation of a permanent spinal catheter and an extended trial period. Several medications will be trialled over a one-two week hospital stay. If the trial is



successful, the pump device is implanted. If the trial is unsuccessful, the catheter will be removed surgically.

4. The implantation of a permanent spinal catheter and drug pump for a 3-6 month 'ambulatory trial' to allow assessment, titration and optimising of the pump medication. If pain is not controlled, the pump and catheter will need to be removed surgically.

There is no one proven or agreed best method for trialling intrathecal drug therapy in all patients. Your treating physician will determine the best method for you.

MEDICATIONS:

Medications commonly used include inactive placebo (saline), midazolam, clonidine, pethidine, bupivacaine, morphine, hydromorphone, baclofen; combinations may also be tested prior to device implantation. Medication related side effects include numbness, tingles, nausea, vomiting, decreased appetite, constipation, itching, fluid retention, urinary difficulties, dizziness, anxiety, muscle weakness, low blood pressure, hormonal changes, sedation, confusion, breathing problems. Withdrawal effects may occur if morphine-like analgesics are weaned and ceased during the trial.

OBSERVATIONS:

For your safety you are closely monitored during the trial and after medication change. Vital signs are recorded every 5 minutes for first 15 minutes, then 15 minutely for 1 hour, half hourly for 4 hours and 4 hourly until medication effect ceases. Pain (or relaxation) symptoms and improvement will be assessed hourly, at rest, with activity and overnight.

INSTRUCTIONS: TRIAL/SCREENING EXTERNAL PUMP:

The intrathecal drug trial using Option 2 or 3 may be continued at home with an external pump to see how you cope with normal activities and determine any side effects.

The following instructions need to be followed for your safety:

1. Check temperature with a thermometer 2-4 times per day. Report any elevation above 38°C.
2. Use ice packs on wounds to reduce swelling, bruising and discomfort for 1-2 days. Report any unexpected redness, inflammation or swelling.
3. Don't get the pump or dressings wet.
4. Sponge baths only - no showers, baths, swimming or soaking.
5. Report to the clinic any severe, persistent nausea, vomiting, severe headache (constant or positional), excessive drowsiness or breathing problems (rate less 8 breaths per minute while awake).
6. Report any profound weakness or numbness occurring after discharge from hospital. Protect and support of the affected area if weakness or paralysis occurs.
7. Resume all routine home medications. Use other pain killers only as directed.
8. Routine activities may be resumed, slowly increase as tolerated. No strenuous activities.
9. **Do not** drive a car or operate machinery or make important decisions within 12h of a new drug.
10. External pumps usually need to be refilled at weekly intervals during trials.



INSTRUCTIONS: IMPLANTED PUMP & CATHETER:

After implantation surgery the pump is programmed and medication adjusted by your pain specialist as needed to control your pain/spasticity. It may take several months of adjustment to obtain the best possible improvement. Please follow your prescribed activity plan and progressively resume your desired activities as tolerated. It is usually safe to return to sedentary work in 2 weeks, more vigorous activities in 4 weeks and most people wanting to work have found and returned to work within 4-6 months.

THE FOLLOWING INSTRUCTIONS NEED TO BE FOLLOWED FOR YOUR SAFETY:

1. Use ice packs on wounds to reduce swelling, bruising and discomfort for 1-2 days. If your pump has been implanted in the abdomen, wearing bicycle shorts or a corset over the pump may help reduce swelling. Please bring a suitable item when you come into hospital.
2. Check your temperature if wound redness or headache, report any elevation over 38°C
3. Report unexpected wound redness, inflammation or swelling as this may indicate infection.
4. Showers may begin 24hours after implantation – keep wounds dry. No tub baths, swimming or soaking until review.
5. Report to the clinic any severe, persistent nausea, vomiting, severe headache (constant or positional), excessive drowsiness or breathing problems (rate less 8 breaths per minute while awake).
6. Report any profound weakness or numbness occurring after discharge from hospital. Protect and support of the affected area if weakness or paralysis occurs.
7. Resume all routine home medications. Use pain killers only as directed.
8. Routine activities may be resumed, slowly increase as tolerated. No strenuous activities.
9. **Do not** drive a car until comfortable, minimise driving in first 2-3 weeks. Watch position of seat belt.
10. Please make an appointment to see Dr. Taverner in 2 weeks or earlier if necessary.
11. Find out when your pump needs to be refilled.
12. The pump program needs to be checked ASAP after a MRI scan. Please arrange to have the MRI on days when the pump can be checked in the clinic after the scan.
13. Avoid ultrasound examinations or short wave diathermy within 10cm of the pump.

EMERGENCY CONTACT

If you have any questions, concerns or problems, call (03) 9770 0522 during office hours. For after hours' emergencies, make your way to the nearest Hospital Emergency Department. Should you be unable to contact our clinic, please call your local doctor or if the problem is urgent attend the nearest Hospital Emergency Department.