

Iontophoresis Clinical Study Fact Sheet

General Information

- The Iontophoresis System provides a means to anesthetize (numb) the tympanic membrane (ear drum) in the office by applying an electric current to deliver a lidocaine/epinephrine (anesthetic) solution to the tympanic membrane.
- The purpose of this clinical study is to test patient experience with the Iontophoresis System, which is not available for sale.
- Once the tympanic membrane has been numbed, the study doctor will proceed with the procedure that is indicated (i.e. myringotomy, tympanocentesis, or tympanostomy with tube implant).

Procedural Details

- The patient will be positioned and prepared for the procedure in the normal fashion for the doctor to clean the ears and to look inside the ears.
- A lidocaine/epinephrine (anesthetic) solution will be warmed to body temperature and placed in the patient's ear. Lidocaine and epinephrine are commonly used anesthetic agents in medical procedures.
- An electrode will be placed on the patient's skin, and another electrode will be placed in the ear. Both electrodes will be connected to the Iontophoresis System.
- The Iontophoresis System will send an electrical current to the electrodes for about 10-12 minutes. When completed, the Iontophoresis System will automatically shut off.
- The patient may feel minor sensation in the ear, but should not feel pain. If the sensation is intolerable at any time, the patient/parent may choose to stop the study and revert to an alternative method of anesthesia.
- Once the Iontophoresis System is turned off, the doctor will remove the electrode and the anesthetic solution from the patient's ear.
- Within 5 minutes of removing the device, the doctor will use an ear probe to test the patient's ear drum for pain. The patient will rate the level of pain using a smiley face chart.
- If the anesthetizing effect is insufficient for the procedure, the patient may inform the doctor and will be treated using an alternative method of anesthesia.
- At this time, the doctor will continue with the indicated procedure (i.e. myringotomy, tympanocentesis, or tympanostomy with tube implant).

Risks and Discomforts

Possible side effects include:

- Tingling, disorientation or nausea due to the electrical current applied.
- Perforation (hole) of the tympanic membrane (ear drum)
- Infection of the ear canal (otitis externa)
- There is a small risk that the electrode will come into contact with the patient's skin and make the ear canal tissue sensitive.
- There is a small risk of damage to structures of the external and middle ear due to mechanical abrasion.

Note: If a patient chooses to participate in the clinical study, full disclosure of the procedure's risks and benefits will be explained in a consent form and by the study doctor.