

Are there any benefits to taking part in this clinical trial?

The Solo+ TTD is designed to make tube insertion easier by combining all the instruments required for the procedure into one device. Possible benefits of having an in-office procedure include avoiding an operating room and general anesthesia, avoiding the need to fast, and a return to normal activities immediately following the procedure.

What will happen to me if I participate in this project?

After the tubes are placed, you will be scheduled to come back to the office for a visit with your healthcare provider an additional 5 times over a 24-month period. These follow-up visits are similar to the routine follow-up visits that occur after tubes are placed in the standard method.

What if I have questions about this project?

You are strongly encouraged to ask any and all questions and read the entire **'Informed Consent for Research'** document for all of the details of this project.

Our clinical research team is here for you so you can best prepare yourself to make an informed decision. Any and all questions are thoroughly encouraged. You can ask them now or at any point. Our contact information is on this pamphlet as well as the **'Informed Consent for Research'** document.

CAUTION: Investigational Device. Limited by Federal (or United States) law to investigational use.

ClinicalTrials.gov Identifier: NCT05741333

Contact Information



Study Coordinator

 NAME

 PHONE

 EMAIL

Physician

 NAME

 PHONE

 EMAIL



The VENTY Study

Clinical Study of the Solo+ Tympanostomy Tube Device

You must thoroughly review the **'Informed Consent for Research'** document to make an appropriate decision. This brief brochure does NOT replace that document.

Why are ear tubes required?

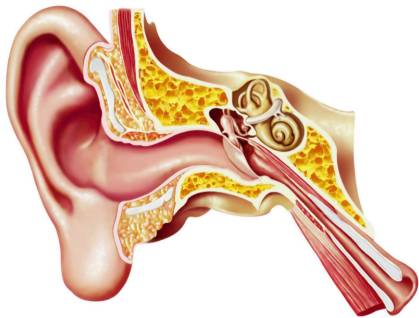
It's not uncommon for children to require ear tubes.

Recurrent Otitis Media (inflammation/infection in the middle ear) or Otitis Media with Effusion (fluid in the middle ear) are very common in children and are the largest reasons for kids to visit the doctor. They can present as a sudden onset of ear pain that may/may not be associated with fever.

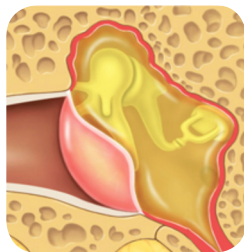
The first treatment option is typically a regimen of antibiotics. If the inflammation/infection persists, longer-term complications can occur (including varying degrees of hearing loss and possible developmental delays).

Doctors may then recommend the insertion of tympanostomy tubes ("grommets", "ventilation tubes", "ear tubes") to help resolve the inflammation/infection.

Anatomy of the Ear



Normal/Healthy Middle Ear



Middle Ear with Otitis Media with Effusion

Why is this project being done?

We are researching a new medical device for inserting tympanostomy tubes. This new device is called the Solo+ Tympanostomy Tube Device (Solo+ TTD).

This study is being done to learn:

- how safe the Solo+ TTD is, and
- how well the Solo+ TTD works



The Solo+ TTD combines all the instruments required for standard tube placement into one product (see image above), allowing doctors to pierce the eardrum and insert tubes with the push of a button. We want to find out how easy the doctor can insert tubes with the Solo+ TTD, and how the tubes perform when they are inserted.

The Solo+ TTD is not yet FDA cleared for sale in the United States. It is considered investigational in the United States.

The Solo+ TTD has received CE mark for commercialization in Europe.

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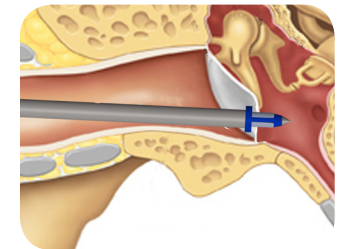
What will happen if I do not participate?

Participating in this study is totally your choice. If you choose not to participate, we will, of course, provide you with the best care possible and you will be treated in the typical way we treat patients with similar conditions.

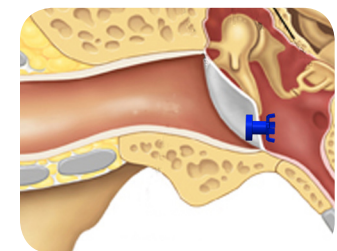
What health risks or problems can I expect from this project?

There are risks in taking part of ANY research project. We carefully watch everyone in the project for problems (side effects). You need to notify the research team immediately if you experience any problems, side effects, or changes in your health (see back of pamphlet for contact information). Please review the **'Informed Consent for Research'** document and discuss any questions with your doctor.

Inserting the Solo+ TTD Tympanostomy Tube



The Solo+ TTD penetrating the eardrum



Solo+ TTD Tympanostomy Tube Implanted