

Informed Consent Form

We invite you to the study, “**Effect of Vaxoral[®] (OM-85) on frequency of upper respiratory tract infections and size of adenoid tissue in preschool children with adenoid hypertrophy**” conducted by Department of Pediatric Allergy and Immunology and Ear-Nose-Throat of Dr. Sami Ulus Maternity and Children Training and Research Hospital. The information or data obtained from your child will be compared to the information or data obtained from the other group of study.

Adenoid pad is a soft tissue like tonsil in the back of throat. A large adenoid pad is one of the most important respiratory problem in preschool children. Upper respiratory tract infections such as common cold, sore throat, swollen adenoid with infection, ear infection (otitis media) and sinusitis are commonly seen in preschool children. However, in some children who have recurrent respiratory tract infections, adenoid pad keeps growing and this can be associated with complications. Swollen (enlarged) adenoids may cause recurrent respiratory infections and each infection contributes to enlargement of adenoid pad thus promoting a vicious cycle.

Swollen adenoids can keep a child from breathing normally through the mouth or nose. If someone stops breathing for short periods during sleep, it is called “sleep apnea”. It can be dangerous. If other treatments do not help, a child might need surgery. Finally, children with swollen adenoid and their parents might have low quality of life. In addition, it causes a burden not only for families but also for healthcare system and society due to increased health cost.

OM-85 (VAXORAL capsule) is an oral product containing the most common respiratory microbes. It acts by stimulating the child's immune system (a system that fights against microbes and diseases). Thus, with the use of Vaxoral, potential benefits can be expected, such as less respiratory infections, less antibiotics using, and preventing further growth of the adenoid pad.

The aim of this study is to investigate the effect of Vaxoral on the frequency of respiratory tract infections and size of the adenoid in children aged 2-6 years with adenoid hypertrophy.

A total of 68 children will be randomly assigned to two groups [Vaxoral capsule and placebo (capsules that have a Vaxoral appearance but no product)]. You and your doctor will not know which of your child has taken it. Three consecutive months, the first 10 days of each month, will be swallowed in the morning. After 6 months, the same treatment will be repeated for 3 months.

Whenever your child becomes sick (cold, flu, fever, sore throat) during this one year period, bring him/her to the Pediatric Allergy-Immunology Outpatient Clinic.

Muayene sonrası sizlerden (anne veya baba veya çocuğun yasal bakıcısı) hastalık belirtileri (burun akıntısı, tıkanıklık gibi), antibiyotik adı ve süresi, kreşe/ana okuluna gidememeyi size verilen kağıda (Form 1) yazmanız istenecektir.

You will be asked to write on the paper (Form 1) that is given to you (parents or the legal guardian of the child) after the examination for the disease complaints (such as nasal discharge, obstruction), antibiotic name and duration, nursery/school absenteeism.

Her 3 ayda bir sizler tarafından geniz eti ile ilgili bir anket (Form 2) doldurulacaktır. Her 3 ayda bir Çocuk Alerji-İmmunoloji Polikliniğine başvurmanız ve evde kaydettiğiniz formları getirmeniz gerekir.

Every 3 months you will be asked to fill in a questionnaire about adenoids (Form 2) and applied our Pediatric Allergy Outpatient Clinic for control.

At 6th, 9th and 12th months of the study, the size of adenoid will be assessed by the ear-nose-throat specialist using "fiberoptic flexible nasopharyngoscopy" (nose examination with a light thin tube). Depending on your child's complaints, additional "fiberoptic flexible nasopharyngoscopy" may be performed if deemed necessary.

At the end of the 12th month, a x-ray (lateral nasopharyngeal graphy) will be taken for the size of the adenoid. During x-ray exposure, it will be exposed to negligible dose of radiation.

You and your child have no responsibility for this research.

This research has no possible risks. Throughout the study period your child will be able to use nasal corticosteroids (nasal spray containing nasal cortisone), antibiotics or antihistamines as needed for swollen adenoid and infections. Vaxoral, which will be given in this study, has been used safely for children older than 6 months for many years.

Side effects with Vaxoral are fairly low. It can be seen nausea, abdominal pain, vomiting, rash, allergic reactions, cough, fever or weakness. Do not use Vaxoral when you have any of these, but you call us (doctors).

If there are any developments that may be of interest to your child during the investigation, this will be notified to you immediately. To get additional information about the study or any problem related to the study, call

No payment will be made to you because of your participation in this study; And you will not be charged for any examinations, laboratory tests and medical care services covered by this research from your social security provider.

Taking part in this study is entirely up to you. You can refuse to participate in the study or leave at any stage of the study; This will not lead to any punishment or any situation that hinders your benefits. If you fail to comply with the applicable requirements or disrupt the work schedule the investigator may remove you from the study by giving you information. The results of the research will be used for scientific purposes; If you withdraw from the study or are removed by the investigator, the medical data about you may also be used for scientific purposes if necessary.

All your medical and identification information belonging to you will be kept confidential and will not be shared with others even in the case of research publication. But the investigator's observers, auditors, ethics committees' and governments' authorities can access your medical information as needed.

Confirmation of Participation to Work:

I have read and verbally listened to the above information which should be given to the volunteer before the investigation started. I ask all the questions that come to mind from the

researcher. I have full understanding of all the explanations made to me in writing and verbally. I have been given enough time to decide if I want to participate in the study. My child was also informed verbally and in detail about the procedures and treatment to be done. Under these circumstances, I authorize the investigator to monitor, transfer and process medical information belonging to my child, and I voluntarily accept the invitation to participate in this research without any compulsion or pressure.

A signed copy of this form will be given to me.

Volunteers'

Name-surname:

Address:

Tel-Fax:

Date and signature:

For those under custody or guardianship, the parent or guardian,

Name-surname:

Address:

Phone-Fax:

Date and signature:

The researcher, who made the explanations,

Name-surname:

Position:

Address:

Phone-Fax:

Date and signature:

Organization officer witnesses, from the beginning of the proceeding to the end of the process

Name-surname:

Position:

Address:

Phone-Fax:

Study name: "Effect of Vaxoral® (OM-85) on frequency of upper respiratory tract infections and size of adenoid tissue in preschool children with adenoid hypertrophy (swollen adenoid)"

Version number: 01

Date:

Informed consent form for children with 2- 6 years old children

You know that there's a disease in your throat right now. For this reason you snore at night, you can not breathe easily, and you often become colds, sore throat. We will treat you by giving you oral medication so you do not get sick often because of your throat/adenoid disease.

The given medication will not cause any pain and it will not hurt.

If you accept, we want to get you a study.

Why did we pick you?

Because this study is done in the same way as yours, in children with swollen adenoid and frequent sickness in the throat. It may be beneficial for you to join the study and for the other children who are sick like you.

What do you expect if you join?

If you agree to participate in the study, you will be given an oral medication for your illness. This medication will not bother you. It will not cause pain. You can swallow it with water or take it in juice for 10 days in the morning.

In addition, before treatment begins, your Ear-Nose-Throat doctor will look at your throat with a thin tube with a camera, while you may feel a slight pain discomfort. In addition, the film of the throat (x-ray) will be shot. In the meantime you will not feel any pain.

Once the blood is taken from the vein, some tests will be done. There will be a slight pain when taking blood. But the nurse who will take your blood will know this job very well and will do it with little pain.

These tests are absolutely necessary tests. If we do not do it, we can not understand if there is any other medication that we should give you, and there may be a problem in the treatment of your disease.

How long will the study last?

It takes 10 days to work. During this time the medicine given to you will be drunk by your mothers once a day You will get this medicine for 10 days within 3

months and then 10 days for 3 months. In the meantime, treatment for the adenoids will continue if necessary (such as nasal spray, nasal wash, antibiotic syrup).

Do you have to join this study?

Participation in this work is entirely up to you. You can refuse to join the study at this time, or you can leave without working at any time after joining. In this regard, you should talk with your parents and decide together whether or not to participate.

If there is anything I want to ask, who can I ask?

Sormak istediğim bir şey olursa kime sorabilirim?

Your mother and father gave the necessary information about this work. You can ask them all kinds of problems, and you can also ask the doctor who is looking at you for all kinds of problems and get information.

You can call the following number 24 hours a day for more information at any time during treatment.

Dr. Serap Ozmen

Phone: