



NEWBORNS WITH SEIZURES

A Quick Introduction to the **PETITE Study**

A Multicenter, Open-Label, Single Arm Study to Evaluate the Pharmacokinetics, Efficacy, and Safety of a Study Drug in Neonates with Repeated Electroencephalographic Seizures (ENS)

Petite 

Why is this study being carried out?

The doctors and nurses taking care of your baby noticed that he/she started to have neonatal seizures. The doctors in your hospital are involved in a research project named PETITE study. It is aimed to look at new ways to treat this type of seizures.

This booklet provides consolidated information about the PETITE study and may help you to decide if this study is of interest to you.

For further information about the study you may also want to take a look at the following web page <http://www.petitestudy.com>.

If you are considering enrolling your baby onto the study, your doctor will speak to you and answer all the questions you may have. You will also receive more detailed information in writing.

Who can participate?

The study might not be suitable for everyone.

If any of the following applies to your baby, this study is not for you:

- Your baby received anti-epileptic-drugs other than those permitted by the study protocol.
- Your baby's condition improved after initial treatment with anti-epileptic-drugs per standard of care.
- Certain blood tests results are outside the normal range.

There are other criteria associated with the medical condition of your baby that may exclude your baby from participation. If you are interested to hear more about the study, your doctor will give you further details.

What are the **potential benefits** and **risks**?

This study has the following benefits for your baby:

- Potential reduction of seizure burden or seizure freedom, but there is no guarantee for this to happen.
- Continuous video and EEG-monitoring (recording of brain waves)
- The option for continued treatment with the study drug in a follow-up study, if deemed beneficial by your doctor.
- Contributing to the advancement of knowledge, which might improve future treatment of babies suffering from seizures.

Taking part in a clinical study can also bear risks. Your doctor will inform you in detail about potential side effects of the study drug and risks associated with study procedures.

What exactly does the study involve?

Study treatment will last up to 96 hours depending on the treatment group your baby will be assigned to. During this period:

- You are free at any time to withdraw your baby from study participation. In this case your doctor will continue the standard treatment.
- Your baby will be monitored around the clock by video and continuous EEG.
- Your baby will be treated with the study drug by intravenous infusion of ~15 minutes 2x/day.
- There will be a series of blood draws. Blood amounts collected each time are ~2 drops.
- You will be informed daily by your doctor or his team about your baby's health condition and the next treatment steps.
- A final safety examination of your baby will follow 1 month after the last administration of study drug. For this purpose, you may be asked to return to the hospital.

How will your participation in the study **affect your baby's treatment?**

As standard therapy, your baby may be treated first with a medication called *phenobarbital*. Alternatively, your baby may receive another anti-epileptic-drug. If this initial treatment does not reduce the seizures, another medication would typically be administered. If you decide to participate in the study, the choice of second line or subsequent treatment will be affected:

- Your baby may be treated with a standard medication and - in addition - receive up to four low doses of the study drug. Or your baby may be treated solely with doses of study drug supposed to be therapeutic.
- If the seizure burden is improving, your baby can stay on the study drug for up to 96 hours.
- If the seizure burden is not improving or even worsening, treatment will be adapted at any time. This means other drug(s) may be administered in addition to the study drug. Alternatively, the study drug may be stopped and completely replaced by other drug(s) used per standard of care.

Creating **new prospects**

Many people have the desire to discover new things and make a contribution to the welfare of others. By participating in the PETITE study, you are supporting an important health research project.

This is the crucial way to further develop new treatment options and to improve the life of newborn babies with seizures.

If you are not interested in the study, this has no impact on the further treatment of your baby.



Your doctor's stamp

This leaflet does not replace an informed consent form or an informed consent conversation with your doctor.

Please speak to your doctor if you would like more information about participating in this study or have further questions.

To learn more about the PETITE study, please also refer to

<http://www.petitestudy.com>