Who can take part in the Stellina Study?

Children with epilepsy who are 2-5 years of age, and use a rescue medication may be able to take part if they*:

- Have epilepsy and experience seizure clusters
- Need rescue medicine at least once every three months
- Weigh between 13 and 73 pounds (6 to 33 kg)
- Have not had major injury or surgery for 30 days before the study

The child's parents or guardians will be told what will happen during the study so that they can decide for their child whether to join the study.

Want to know more?

www.neurelisclinicalstrials.com

What happens at the end of the study?

After your final follow-up visit, you and the study participant will have an opportunity to join the **Stellina Extension Study**. During the extension the participant will receive the investigational drug for up to an additional one year. The purpose of this extension is to assess the safety and effectiveness of the investigational drug in this population.

*Additional eligibility criteria apply.

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If your child has epilepsy, is 2-5 years of age, and uses a rescue medication, you might be interested in the **Stellina Study**.

Want to know more?

www.neurelisclinicalstrials.com

You can also learn more by visiting

www.clinicaltrials.gov

www.valtoco.com

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The Stellina Study

A Phase 1/2a clinical study evaluating a single dose of diazepam intranasal spray (VALTOCO®) as a rescue medication in children aged 2-5 who have been diagnosed with epilepsy.

What are clinical research studies?

The aim of clinical research is to help people live longer, healthier lives. To achieve this, researchers develop drugs to improve the treatment and prevention of disease. Testing of investigational drugs takes place in clinical studies.

What is the Stellina Study?

The Stellina Study is a Phase 1/2a clinical study evaluating a single dose of diazepam nasal spray (VALTOCO®) as a rescue medication in children aged 2-5 who have been diagnosed with epilepsy. The objectives of the study are to assess the pharmacokinetics (PK) of diazepam (looking at levels of diazepam in the child's blood) after one intranasal dose of VALTOCO as well as assessing the long-term safety and tolerability in the six-month open-label safety period.

What is VALTOCO, the study drug the child will receive?

VALTOCO is a medication used as a short-term treatment for episodes of frequent seizures in adults and children with epilepsy 6 years of age and older.

It is a nasal spray with diazepam. Diazepam rectal gel (Diastat®) is also used to treat seizure clusters in children at least 2 years old.

To learn more about VALTOCO, please visit www.valtoco.com to see the full prescribing information, including the boxed warning.

What are episodes of frequent seizures?

These are typically two or more seizures in a day which may also be called seizure clusters, acute repetitive seizures or seizure flurries, and other names.

What happens during the study?

Part 1
Screening (up to 21 days)

The study doctor will perform some tests to check if your child is eligible for the study.

Part 2
Baseline Dosing (1 day)

One dose of the study drug, diazepam nasal spray, will be given while the child is not having a seizure. The doctor will check your child's blood over a six-hour period. Study drug will be provided to the caregiver and patient to take home.

Part 3
Safety Period (26 weeks)

Study drug will be given as needed at home by the caregiver. Safety events will be collected during this period. There will be three visits to the office and four phone calls to gather information about the patient.

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