This document provides a short summary of this study for a general audience. You can find more information in scientific summaries of the study. Links to those summaries are provided at the end of this document.

Study Identification

Short Title: A study of lamotrigine used alone in children with typical absence seizures.

Full Scientific Title: A multi-center, uncontrolled, open-label, evaluation of lamotrigine monotherapy on newly diagnosed typical absence seizures in children and adolescents.

Name and Contact Details of the Sponsor

GlaxoSmithKline (GSK)
GSK Clinical Support Help Desk
Website: http://www.clinicalsupporthd.gsk.com/
Email: GSKClinicalSupportHD@gsk.com
Telephone Number: +1-438-899-8201

General Information about the Study

Study Dates

The study started in September 2011 and ended in November 2015.

The Main Objective(s) of the Study

The objective of this study was to see how well a medicine called lamotrigine treated children in Japan and South Korea who had a certain type of seizures called typical absence seizures. The results of the study provide information to help a government agency in Japan make a decision about approving lamotrigine for typical absence seizures.

Typical absence seizures are short periods when the person stops what they are doing and stares blankly. These seizures may occur many times per day. The person may seem like they are daydreaming, but they can't react if someone approaches them.

Participants

Study Site Locations

Study sites were located in Japan and South Korea.

Patients Included

Patients in this study were children who had been diagnosed with typical absence seizures but had not started treatment (treatment naïve).

Each patient had to weigh at least 7 kg (15.4 pounds) and could not be in the study if they had a history of getting a rash from other types of medicine or also experienced other types of seizures.

Of the 20 patients in the study, 16 were from Japan and 4 were from South Korea. Thirteen patients were girls and 7 were boys. The youngest patient in the study was 4 years old and the oldest was 12 years old. The average age of patients in the study was 7.7 years old.

Investigational Medicinal Products Used

Medicines used

All patients in the study were treated with lamotrigine. There was no comparison with other medicines and eveyone knew the medicine they were taking was lamotrigine.

Patients started with a low dose of lamotrigine. At each visit to the study doctor, the dose was increased until the patient did not have a seizure when a trigger test for seizures was used. The trigger test used in this study was having patients breathe quickly with shallow breaths (hyperventilate). Hyperventilating can bring on an absence seizure. Each patients' appropriate dose was confirmed by a normal brain wave pattern without seizures using electroencephalogram (EEG) testing. Each patient was then given a dose one level higher to continue for 12 weeks (the maintenance phase of the study).

Results of the Study

Results

An appropriate dose of lamotrigine was found for all 20 patients in the study. At the end of the maintenance phase, 7 of the 20 (35%) patients remained seizure-free, as they had not had a seizure when asked to hyperventilate.

Description of Adverse Reactions and Their Frequency

Adverse Reactions

The table below looks at the safety of lamotrigine. The table lists the adverse events that the study doctors (investigators) thought were related to lamotrigine.

The Number and Percentage of Patients Who Reported Adverse Reactions	
Adverse Reaction	**Number (Percentage)**
Rash	5 of 20 (25%)
Headache	1 of 20 (5%)
Overactive behavior (Psychomotor hyperactivity)	1 of 20 (5%)
Drug allergy (Drug hypersensitivity)	1 of 20 (5%)

Comments on the Outcome of the Study

What did this study tell researchers?

In this study, approximately a third of the patients with typical absence seizures had no seizures at the end of the maintenance phase. The most common adverse reaction was rash. This was a Phase III study. Phase III studies gather information to help regulators make decisions about approving a medicine for a condition in their country. This summary shows the results from one study. Other studies may have different results.

We would like to thank the patients who contributed and their parents.

Further Studies

Currently no future studies of lamotrigine in patients with typical absence seizures are planned.

Where Additional Information Can Be Found

Clinical studies have unique study numbers, which are included in scientific publications and other information sources. Below are the unique study numbers associated with this study. The hyperlink text connects to scientific summaries and other information on the Internet.*

Organization	Website	Study Number
United States National Institutes of Heath (NIH)	www.clinicaltrials.gov	NCT01431976
GlaxoSmithKline (GSK)	www.gsk.clinicalstudyregister.com	115377

Your doctor can help you understand more about this study. You should not make treatment changes based on the results of this or any single study. Continue with the current treatment unless instructed by the doctor.

This document was developed and approved by GSK on January 4, 2017. The information in this summary does not include additional information available after this date.

*For readers of this document in text form, the websites associated with the hyperlinks above are
http://www.gsk-clinicalstudyregister.com/study/115377?study_ids=115377#rs
https://clinicaltrials.gov/ct2/show/NCT01431976?term=115377&rank=1