ZEALAND PHARMA

THE ZEALAND
Pediatric Type 1 Diabetes Study
is Searching for a Hypoglycemia Treatment

Information for Patients
ClinicalTrials.gov Identifier: NCT05378672

Protocol Title: A Phase 3, single-administration, open-label trial to assess the efficacy, safety, pharmacokinetics, and pharmacodynamics of dasiglucagon when administered as a rescue therapy for severe hypoglycemia in pediatric patients below 6 years of age with Type 1 Diabetes (T1D)

Protocol Number: ZP4207-21052

Welcome to the Zealand Pediatric Type 1 Diabetes clinical research study.

You understand the challenges that come with managing your child's blood sugar. That's why we need your help to evaluate the effectiveness and safety of an investigational therapy for the treatment of hypoglycemia (low blood sugar) in children less than 6 years of age with Type 1 Diabetes (T1D).

The Zealand Pediatric Type 1 Diabetes Study

This study is designed to assess the safety and efficacy of dasiglucagon when administered as a rescue therapy for severe hypoglycemia in pediatric patients below 6 years of age with T1D.

The purpose of this trial is to investigate if a single dose of 0.3 mg or 0.6 mg dasiglucagon is safe, well-tolerated by children less than 6 years of age, and to measure the concentration of glucose and dasiglucagon in your child's blood when dasiglucagon is used as a rescue treatment for hypoglycemia.

Your child is being asked to participate in this study because your child has T1D.

To participate in this study, your child must meet these criteria:

- Must have a confirmed T1D diagnosis based on medical history
- Must be receiving daily insulin therapy via insulin pump or multiple daily injections (MDI)
- Must weigh more than 8 kg (17.6 pounds)
- Must have signed consent form by a parent or legal guardian

If you choose to have your child take part in this trial, your child will be one of approximately eight patients below 6 years of age who will be enrolled across approximately five sites in the United States. Other criteria to join the study will also apply.

As a participant in the Zealand Type 1 Diabetes Study you will receive:

A single dose of 0.3 mg or 0.6 mg of dasiglucagon

Reimbursement for your travel expenses to and from the clinic and / or travel booking may be provided

Study-related blood tests, physicals, safety monitoring, and on-site medical care

T1D & DAISGLUCAGON

T1D can be exhausting.

T1D is a condition that prevents your child's body from producing insulin, a hormone used to store sugar in blood cells. This means a higher concentration of sugar in your child's bloodstream, which can result in damage to your child's blood vessels, eyes, kidneys, and heart. Most commonly, symptoms can manifest as exhaustion, tiredness, or extreme hunger or thirst.

The cause of T1D is unknown, and there is currently no cure.

Dasiglucagon may be able to help.

Glucagon is a natural hormone occurring in the body that raises the blood sugar concentration. Dasiglucagon is a glucagon-like substance that has similar properties as glucagon. The effect of glucagon is opposite to that of insulin, as glucagon increases the blood sugar. Thus, glucagon and insulin are important regulators for maintaining a constant blood sugar level.

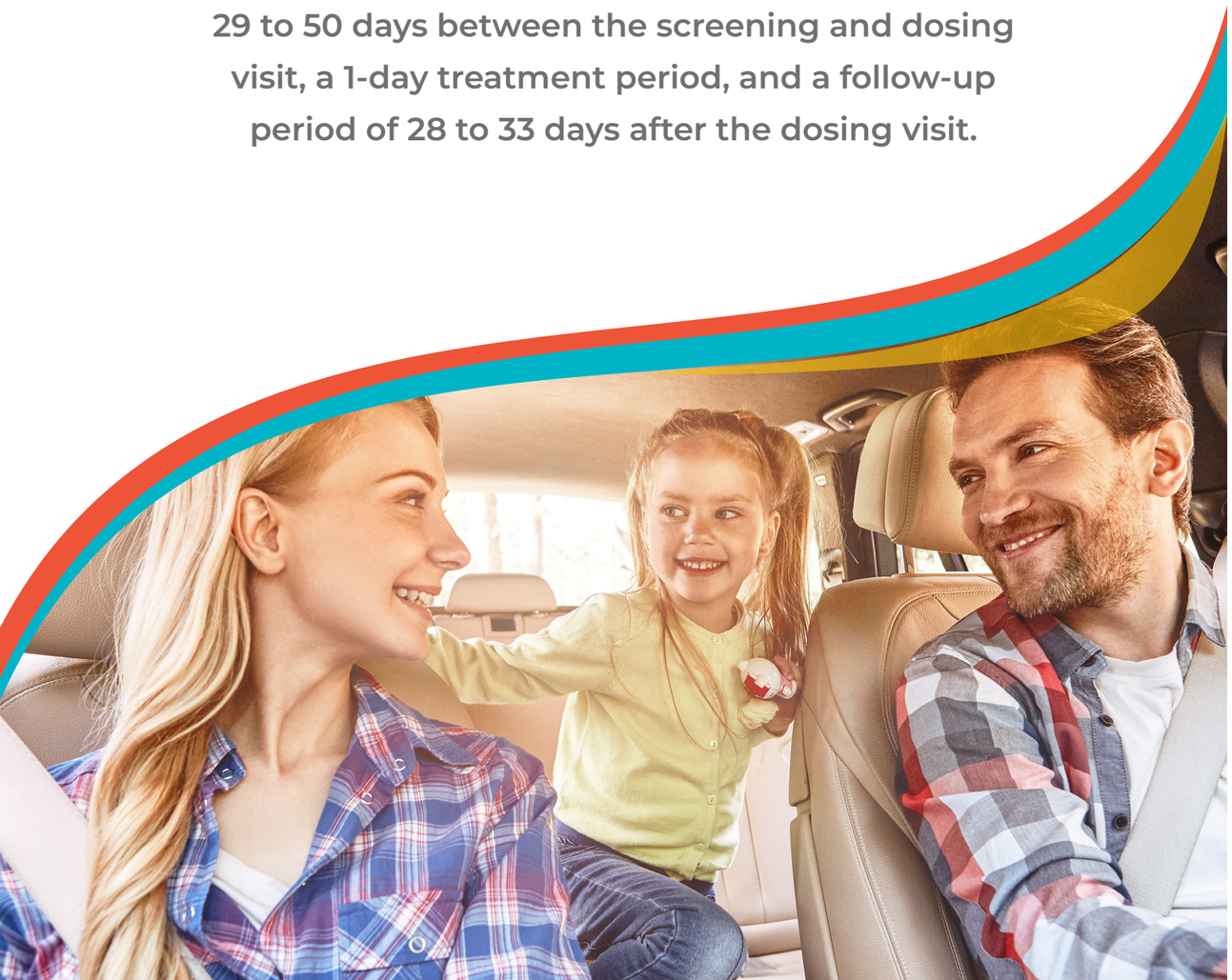
FDA Approved

Dasiglucagon is approved by the Food and Drug Administration (FDA) for the treatment of severe low blood sugar concentration (hypoglycemia) in pediatric and adult patients with diabetes aged 6 years and above.

STUDY OVERVIEW

The trial has three scheduled trial visits:

Your child's participation in this clinical trial is expected to last for up to 84 days. This includes 29 to 50 days between the screening and dosing visit, a 1-day treatment period, and a follow-up period of 28 to 33 days after the dosing visit.



A SCREENING VISIT | VISIT #1

- Trial doctor will verify participation criteria
- Trial doctor will perform physical and medical history examination
- Trial doctor or nurse will take blood samples and run tests (including vital signs, and electrocardiogram (ECG))
- Your child receives ID card indicating participation in the trial and whom to contact

A DOSING VISIT | VISIT #2

This will occur 4 to 7 weeks after the screening visit

- Trial doctor will perform similar physical examination as visit 1
- Study staff will fit your child with a Dexcom G6 continuous glucose monitor (CGM) System to measure blood sugar levels during the visit
- Your child's vital signs will be measured
- Your child will receive insulin infusion into the vein until your child's blood sugar level drops to the lower levels of normal
- Your child will receive one dose of 0.3 mg or 0.6 mg dasiglucagon injected under the skin of your child's buttocks
- Your child will have blood samples taken
- Trial doctor will check for any problems at injection site

A FOLLOW-UP VISIT | VISIT #3

This will occur 4 weeks after previous dosing visit

- Trial doctor will perform similar physical examination as visit 1
- Trial doctor will check for any problems at injection site
- You and your child will talk about how your child is doing since the last visit
- Your child's vital signs will be measured
- Study staff will take blood samples

Safety & Risks

The safety of dasiglucagon is expected to be similar in children under 6 years of age as in older children, for which dasiglucagon is approved by the FDA. The most common adverse effects of the treatment with dasiglucagon have been mild or moderate and temporary. In children aged 6 to 11 years, nausea and vomiting occurred in one of four patients. Experience with commercially available glucagon describes that in rare cases some patients have experienced allergic reactions.

Other potential risks include:

- Blood sugar too high (hyperglycemia)
- Rapidly changing blood sugar
- Development of antibodies against dasiglucagon
- Inflammation from blood collection and use of indwelling intravenous cannulas (a small flexible tube placed into a vein for administering insulin / glucose and for blood draws)
- Skin irritation from ECG pads
- Skin irritation from CGM System
- Side effects or discomforts that are not listed here

Cost, Compensation, and Benefits

With the exception of medical examinations, your child is not likely to get any personal health-related benefits from participating in this trial. If your child takes part in this trial, children with T1D may benefit from this research in the future.

Dasiglucagon and all tests, procedures, and visits required for this trial will not cost you anything. The study sponsor will pay for them. Expenses (e.g., travel) will be reimbursed after receipts for these payments are provided and in agreement with the trial doctor. The costs of other drugs and treatments that you take or use independently of this trial are not covered by the sponsor of this trial.

Privacy & Data

Certain people and organizations will be given access to see, copy, and use your child's health data so they can do their part in this trial. It may be possible that these data can be traced back to you and your child, even if the data does not include your names. Your child's health data will need to be shared for the research and other reasons. Therefore, complete privacy of your child's health data cannot be promised. However, sharing your child's health data will be guided by professional standards and the law.

Your child's data must be shared with certain people and organizations necessary for this trial to be conducted. Your child's data will be shared for research purposes only and will be done so under guidance of professional standards of the law, but complete privacy of your child's health data cannot be promised.

You have the right to ask for your child's personal data. You also have the right to ask for your child's personal data to be corrected or deleted. Additionally, you may withdraw from your participation in this trial at any time; however, data already collected will be used for analyses defined in the trial unless stated otherwise by local regulation.

What is a Clinical Research Study?

Clinical research studies test investigational therapies to determine their safety and effectiveness before they are approved and made available to the general public. Participants are critical to bringing life-changing new therapies to patients. To protect participant rights and safety, clinical research studies have strict eligibility criteria and are reviewed and approved by institutional review boards and / or ethics committees before participants are included.

Studies are conducted in phases and at various doses. Phase 1 and 2 studies test an investigational drug's safety and collect initial data on effectiveness. Phase 3 studies evaluate whether the investigational drug is effective at the dose determined in previous studies. The Zealand Pediatric T1D Study is a phase 3 study; therefore, there is a body of established data gathered from previous participants in phase 1 and phase 2 studies that indicates it may be safe and effective.

Taking part in this study is voluntary. You can decide to stop taking part at any time.

Go to ClinicalTrials.gov for more information about the study and to see if you may qualify.

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20230509–US–ENG–PI–BRO–ZP4207-21052–V2.1