



eHRIS

Learns about a
potential new
treatment for
**congenital
hyperinsulinism!**

CHRIS

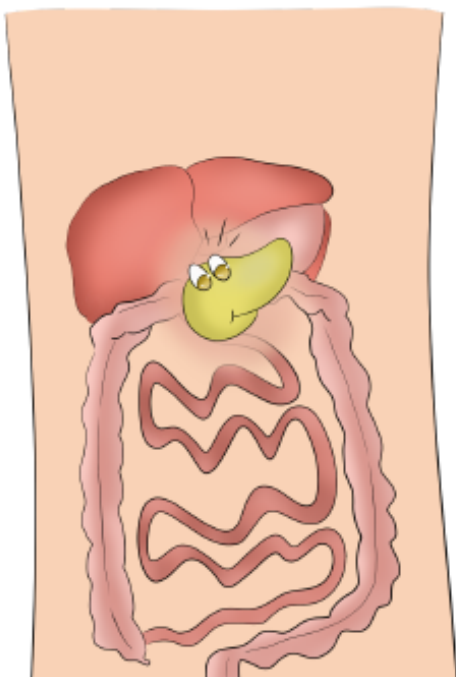
was born with
**CONGENITAL
HYPERINSULINISM**
(CHI).

In children with **congenital** (born with) **hyperinsulinism** (too much insulin), or CHI for short, more **insulin** is sent from the **pancreas** than is normally required.

The extra **insulin** keeps taking sugar from the **bloodstream** to store away for later, even though they do not have enough sugar to run on properly right now. Because of this, the **levels of sugar in the blood are low**, and a low blood sugar can make them **feel sick**.

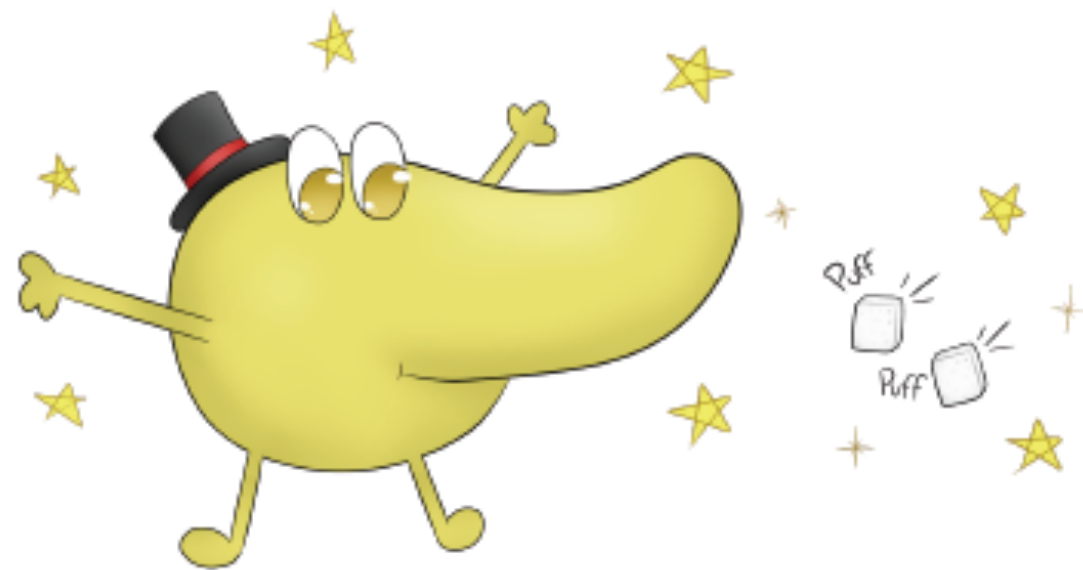


We are all born with a
small organ in the belly
that is called the
PANCREAS.



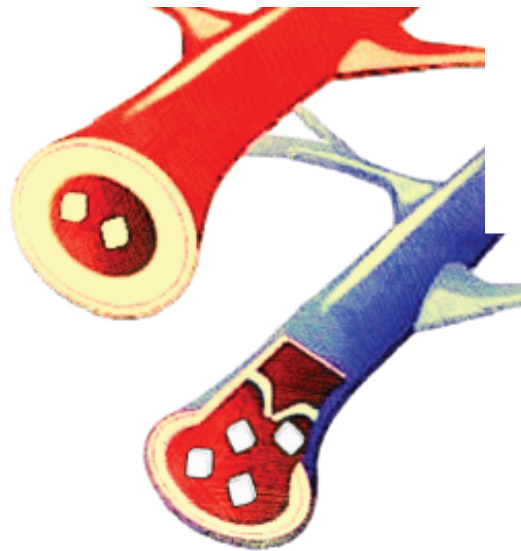
It is located behind
the stomach
and in front of
the back bone.

The **PANCREAS**
helps our body use
the food we eat.



One way
the **pancreas** helps
is to make
INSULIN.

INSULIN
tells the body
to take the
SUGAR
in the blood



into places where
it can make
ENERGY
to do the things
you like to do,

An illustration depicting three scenes of a boy's activities. In the top left, a boy in a red shirt runs while holding a colorful kite. In the bottom left, a boy in a green shirt runs with a soccer ball. In the bottom right, a boy in a yellow shirt runs. Above the kite, a blue character with a white cube is shown, representing energy being used for these activities.

like **swim**, or **run**
or **PLAY**.

Too much

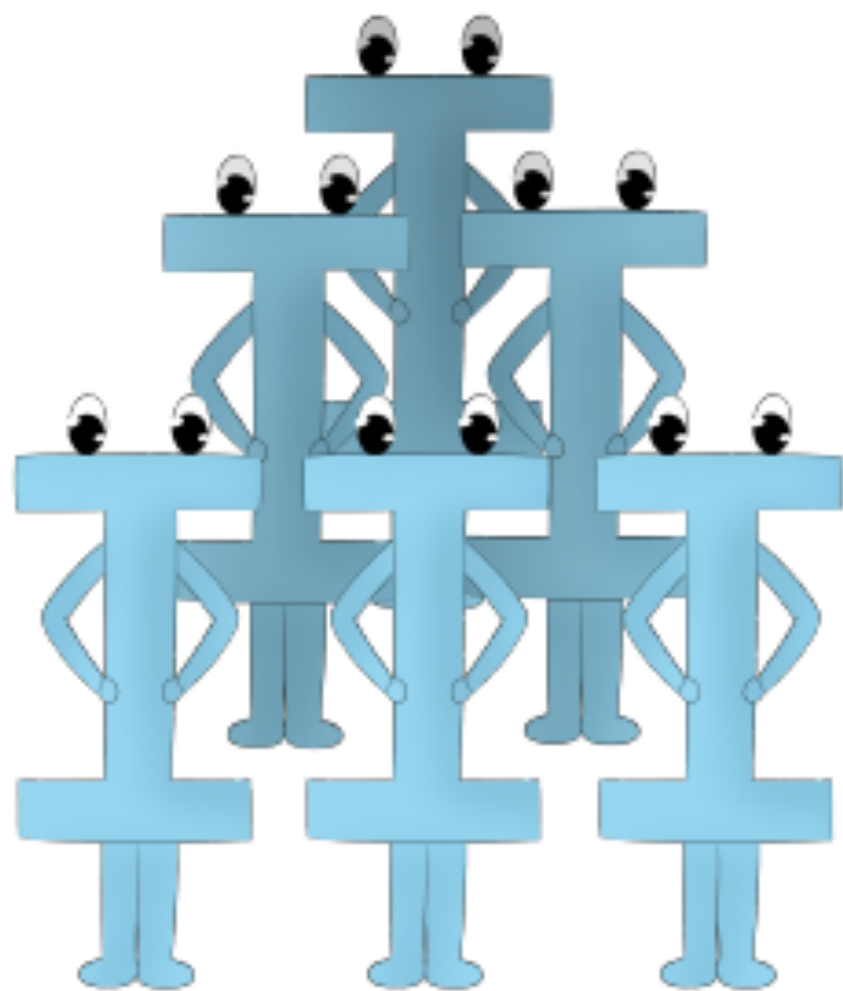
INSULIN

can be harmful for

CHRIS' body,

especially

CHRIS' BRAIN.

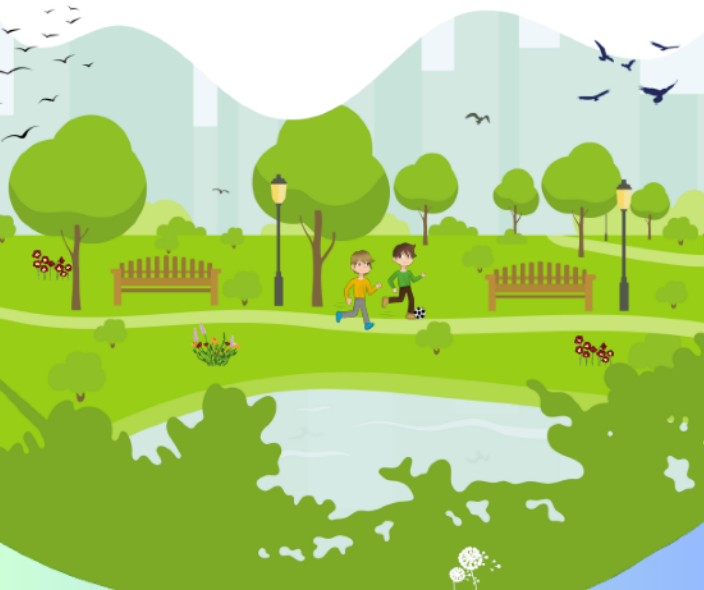


A company called
REZOLUTE
is trying to make a
new treatment
for **CHI**.



To know for sure if **RZ358** is safe
and helps keep blood sugars in a
healthier range, **Rezolute** will test the

TREATMENT
in babies, kids
and grown-ups with **CHI**.



The
new treatment
is named
RZ358



in a
study called
RZ358-301
(also called



To help
CHRIS
understand
more about
RZ358



Here are some common

QUESTIONS

and

ANSWERS.



What does **RZ358** do ???



RZ358'S job is
to **turn down**
the signal from

INSULIN

and stop it from
taking **too much**

SUGAR

from the blood.

Have others **tried**
RZ358 before ???



75 participants have received
RZ358 in **6** clinical studies so far:

22 healthy adult volunteers

16 adults with post-gastric bypass
hypoglycemia

11 adults with congenital HI

26 pediatric patients with congenital HI
- **16** patients ages 2-6 years old

Have others **tried**
RZ358 before ???



RIZE
RZ358-606

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* Bulgaria



* Denmark



* Germany



Georgia



United States



UK
(England)



Turkey



Israel



* Spain

Is it safe to take **RZ358** 

The **RIZE** study showed that it was safe and well-tolerated,
but what does that mean?



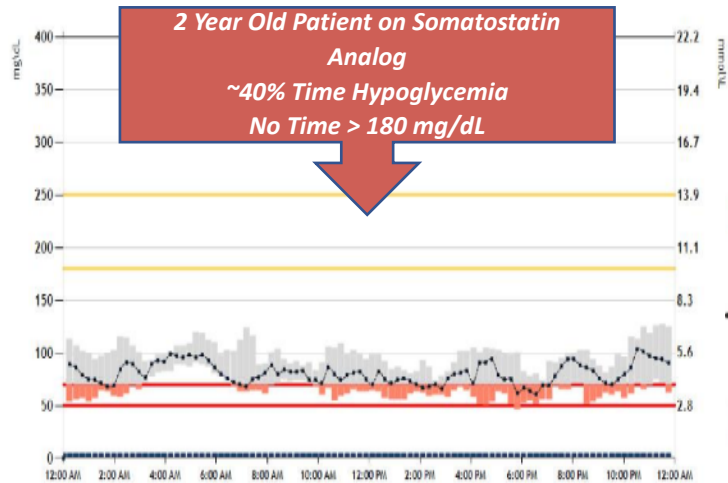
- No one stopped the study early due to “adverse effects”
- Three (3) patients experienced four (4) “adverse effects” felt to be related to **RZ358**
 - Dizziness, ‘hyperactivity’ and site rash/discomfort

What happened to blood sugars when kids took

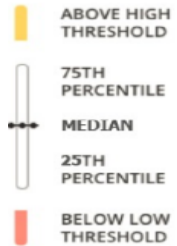
RZ358



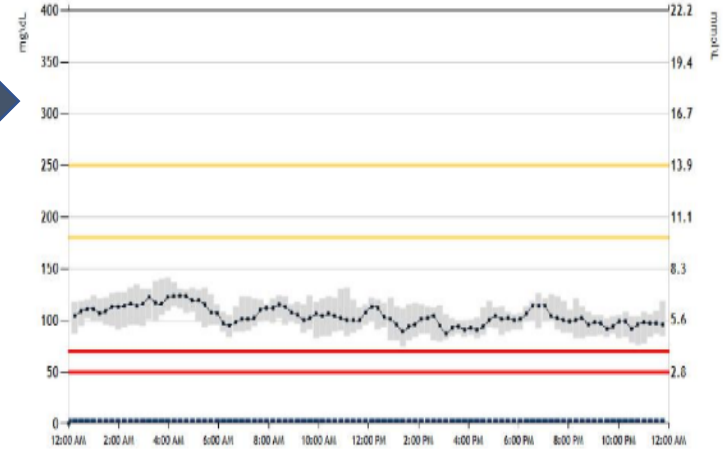
Baseline CGM period (≥ 10 days)



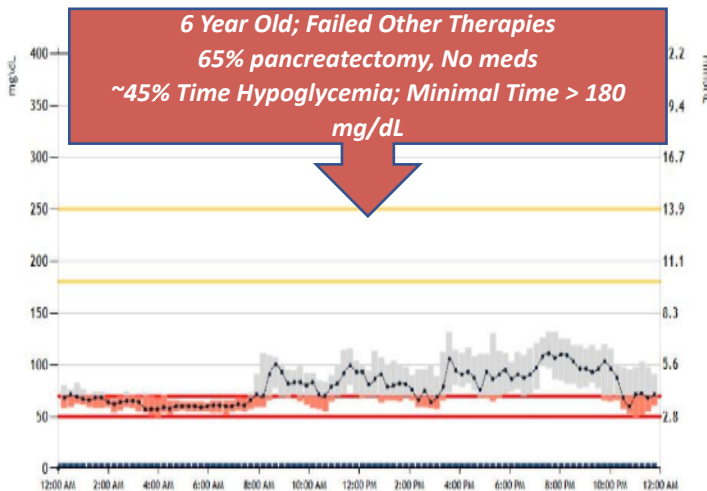
+ RZ358 (6 mg/kg)



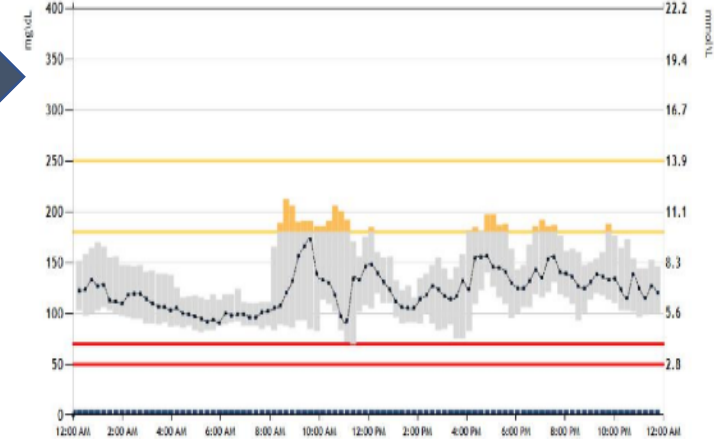
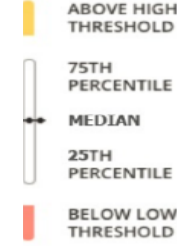
Treatment Evaluable CGM period (2-weeks)



Baseline CGM period (≥ 10 days)



+ RZ358 (9 mg/kg)



What ELSE happened to blood sugars when tr **RZ358**

Responders N (%)	RZ358 6 mg/kg (n=8)	RZ358 9 mg/kg (n=7)
≥25% Correction of Hypoglycemia		
Severe (<50 mg/dL)	7 (88%)	7 (100%)
Overall (<70 mg/dL)	7 (88%)	7 (100%)
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Severe (<50 mg/dL)	5 (63%)	6 (86%)
Overall (<70 mg/dL)	3 (38%)	5 (71%)

What ELSE happened to blood sugars when treated with **RZ358**??

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A **MOM** shared her thoughts



- Participating in the RIZE trial was the best thing that could have happened to us because [daughter] was able to **regulate her glucose** values much better.
- In these weeks [daughter] has only needed 2 juices to treat low blood sugar and any **hypoglycemia** that has occurred **has not been as serious** as the ones she had before RZ358.
- We have managed to significantly **reduce her intake of carbohydrates** with which she is beginning to **lose weight**.
- We have also achieved a **better tolerance to proteins**, even having dinners with only proteins; something completely impossible before because it meant being less than 50 mg/dl at 30 minutes.
- Because she is much better, it is the first year that she has been able to **start extracurricular sports at school** two days a week.
- As she is better, she has also been able to go to **sleep at a friend's house**; something completely unthinkable before.
- We have managed to go on a **2-hour excursion walking without any hypoglycemia**.

Phase
2b

RIZE
RZ358-606



* Bulgaria



* Denmark



* Germany



Georgia



United States



UK (England)



Turkey



Israel



* Spain

Phase 3



* Bulgaria



* Denmark



* Germany



Georgia



United States



UK (England)



Turkey



Israel



* Spain



Qatar



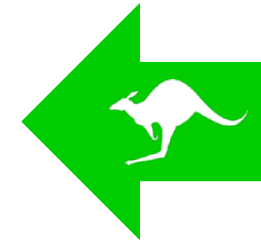
Saudi Arabia



Oman



Australia



Vietnam



* France



Canada



* Greece

Can I still **participate** if I live far from the nearest **study site**



YES

Rezolute has partnered with a company that **specializes** in **helping** participants with study-related **travel and costs**



Scout Clinical offers a stress-free, confidential, and personalized process for getting patients to and from clinical treatment centers anywhere in the world. We have over 20 years of experience specializing in travel and expense management for clinical trials.

How Can Scout Help My Patients?

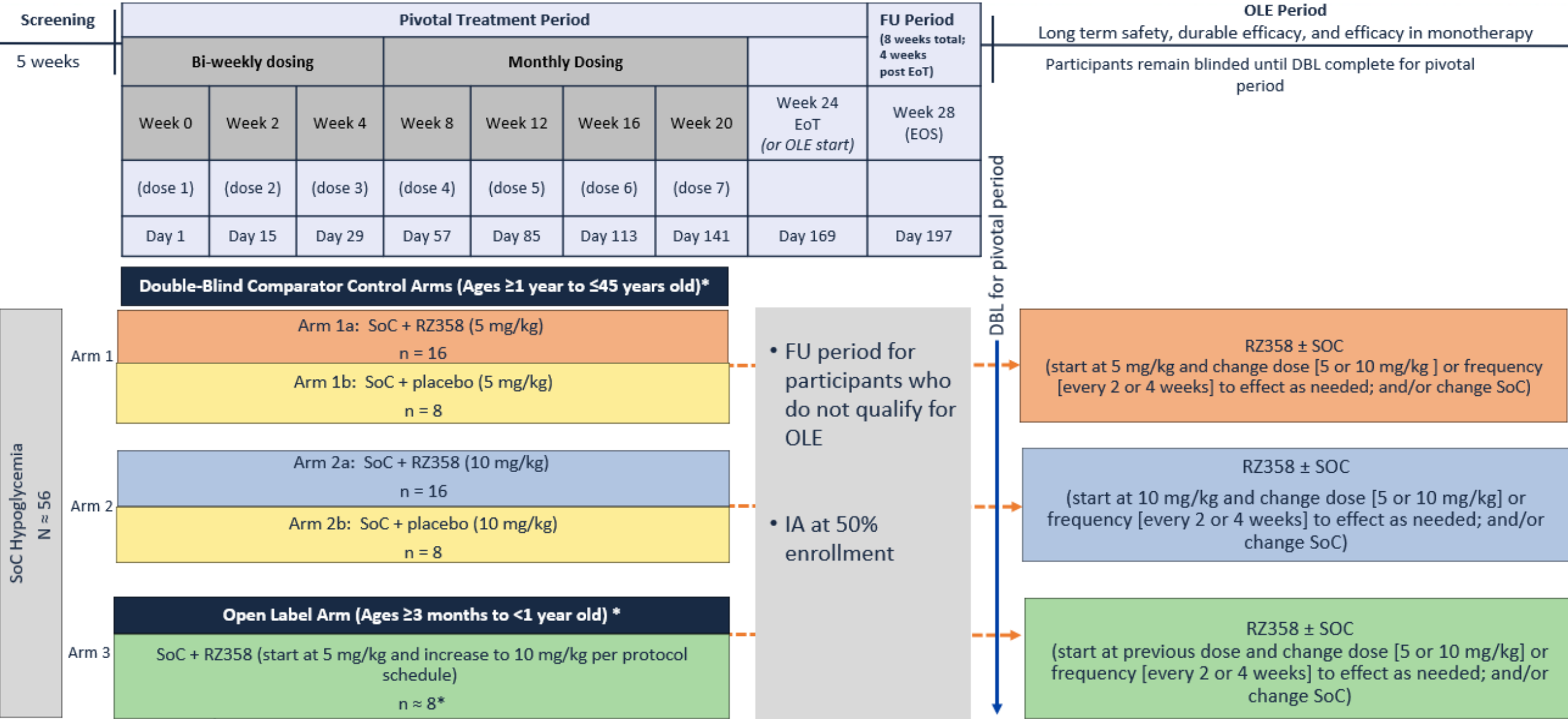
After the patient has consented to participate in the <Clinical Trial Name>, and if they would like to take advantage of Scout Clinical's patient travel and expense management services, simply add the patient to your study at portal.scoutclinical.com or contact us at info@scoutclinical.com.

What Can the Patient Expect?

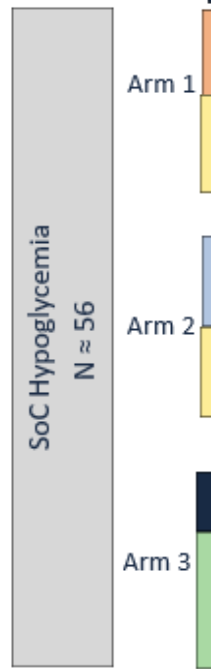
- A comprehensive itinerary covering air/rail travel, transportation, and lodging.
- Expense management through bank transfer, Scout Pass, or check.
- 24/7 live customer support available in multiple languages.

For next steps, log-in at portal.scoutclinical.com or contact Scout Clinical at :
USA: +1 214 586 0020 (Toll-Free: 800-601-0012)
UK: +44 207 307 9906 or email: info@scoutclinical.com



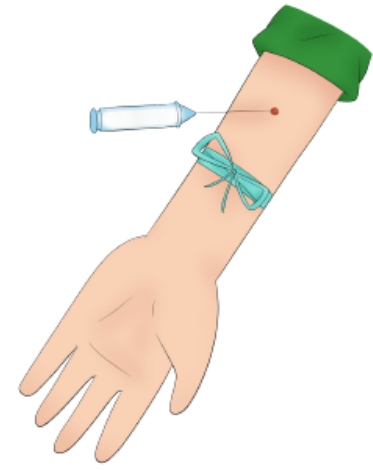


Screening
5 weeks

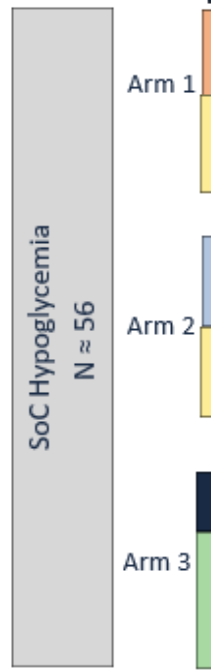


Screening
5 weeks

eHRIS will be given a new **GLUCOMETER** and **CGM** to use during the study.



to help the doctor decide if **eHRIS** is healthy enough to be in the study and is still having low blood sugars, a few tests of **BLOOD** will be done.



eHRIS will also have special heart and tummy tests several times in the study.

Pivotal Treatment Period								FU Period (8 weeks total; 4 weeks post EoT)
Bi-weekly dosing			Monthly Dosing					
Week 0	Week 2	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24 EoT (or OLE start)	Week 28 (EOS)
(dose 1)	(dose 2)	(dose 3)	(dose 4)	(dose 5)	(dose 6)	(dose 7)		
Day 1	Day 15	Day 29	Day 57	Day 85	Day 113	Day 141	Day 169	Day 197

Double-Blind Comparator Control Arms (Ages ≥1 year to ≤45 years old)*

Arm 1	Arm 1a: SoC + RZ358 (5 mg/kg) n = 16
	Arm 1b: SoC + placebo (5 mg/kg) n = 8

Arm 2	Arm 2a: SoC + RZ358 (10 mg/kg) n = 16
	Arm 2b: SoC + placebo (10 mg/kg) n = 8

Arm 3	Open Label Arm (Ages ≥3 months to <1 year old) *
	SoC + RZ358 (start at 5 mg/kg and increase to 10 mg/kg per protocol schedule) n ≈ 8*

- FU period for participants who do not qualify for OLE

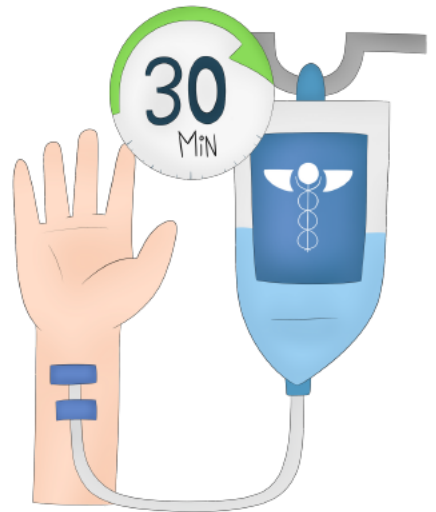
- IA at 50% enrollment



How is **RZ358**
given???

RZ358 is given through a
small tube inserted into a vein
called an **IV**.

A dose takes about
30 minutes to go
through the **IV**.

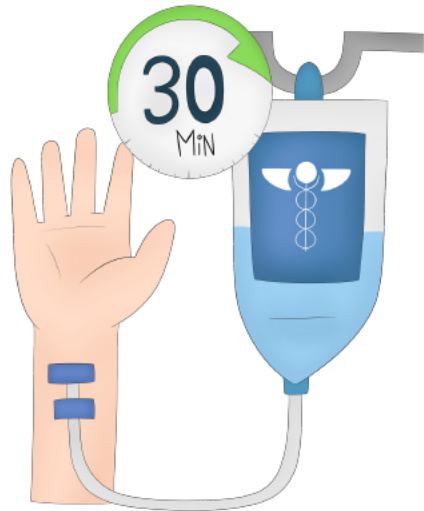




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Does it hurt to get **RZ358** ???
It **might hurt** a little when the **small tube** is put into a vein (usually in the **hand** or **arm**).



eXRis might also have some **itching**, **slight headache** or **dizziness** during or shortly after the medicine goes in the body.

How does the **STUDY** help others learn how **RZ358** may be helping other parts of **my life ???**



At certain times
during the study,
CHRIS' mom or dad
will write down what
CHRIS eats or drinks.
They will also **answer**
special **QUESTIONS**
about what **CHRIS**' life
with **CHI** is like.

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Will I need to sleep at the **HOSPITAL ???**



There are **NO** nights where **CHRIS** will have to sleep in the **HOSPITAL** for this study.

OLE Period

Long term safety, durable efficacy, and efficacy in monotherapy

Participants remain blinded until DBL complete for pivotal period

→ RZ358 ± SOC
(start at 5 mg/kg and change dose [5 or 10 mg/kg] or frequency [every 2 or 4 weeks] to effect as needed; and/or change SoC)

→ RZ358 ± SOC
(start at 10 mg/kg and change dose [5 or 10 mg/kg] or frequency [every 2 or 4 weeks] to effect as needed; and/or change SoC)

→ RZ358 ± SOC
(start at previous dose and change dose [5 or 10 mg/kg] or frequency [every 2 or 4 weeks] to effect as needed; and/or change SoC)

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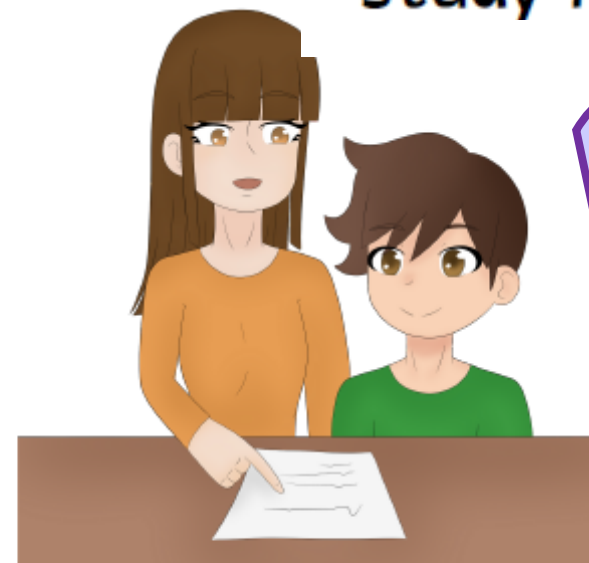
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What happens after the study ends

If his mom or dad and doctor think CHRIS should keep taking RZ358, CHRIS can stay in the study for longer.



Open Label Extension

What
questions do
you have
about **RZ358** 

