

WHAT DO PARENTS DO: BEFORE & DURING THIS STUDY

Prep



At-Home (Before Study Begins!)

Download/print forms* found on the KCNT1 Foundation's website.

- Review the **study information** and **Informed Consent Form**. Email the Foundation if you would like a consent form to be emailed to you.

If possible, sign the consent form now. You can also schedule time to talk with Study Coordinator(s) & ask any questions!

- Print the 14-day **Screening Diary**. Complete the diary for 2 weeks (or per your doctor's instructions). Your doctor will use this info to decide if carvedilol makes sense for your child.

- Print **Doctor Launch Packet A** for your upcoming doctor appointment. It should include 2 forms.

- Schedule your first appointment with your doctor to discuss carvedilol.

**If you prefer paper forms or can't access the website, we can also mail them to you! Contact us info@kcnt1epilepsy.org*

STUDY CONTACT INFO

General Email:
manager@kcnt1epilepsy.org

Study Coordinator:
KaitlynE@Kcnt1epilepsy.org

Month 1



1st Doctor Visit

- Bring your completed **Screening Diary(ies)** and the **Doctor Launch Packet A** to your appointment to review with your doctor. Go to your appointment. At the appointment, you'll talk about medical history and review the completed **Screening Diary(ies)**.

If your doctor prescribes carvedilol as part of your child's care plan, you will formally join the study here. The informed consent form must be signed by this point. Contact Study Coordinators with questions and to receive your unique Study Folder Link.

- Your doctor should complete the forms in **Doctor Launch Packet A** during your appointment. Please collect the form before you leave. If it's incomplete or you forget it, collect it from your doctor's office via email or mail.

- Scan or take a picture with your device of all the forms in **Doctor Launch Packet A** and the **Screening Diaries**.

- Upload the scans/pictures of the **Screening Diary(ies)** and **Doctor Launch Packet A** to Study Coordinator(s) via your Study Folder Link.



At-Home After 1st Doctor Visit

Continue to track daily symptoms! Complete the following surveys after that first doctor visit.

Daily Tracker Diary:

- Print **Daily Tracker Diary** (seizure and heart rate form) and complete for the first full week each time you are prescribed a new dose.

Complete the following surveys after downloading them from the KCNT1 Epilepsy Foundation website and submit with your Daily Tracker Diary to a Study Coordinator:

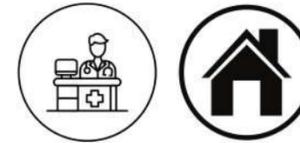
- CCSA-Caregiver Survey
- KCNT1 Demographics
- Medications

Submit your information!

- After 1 week, scan or take a picture with your device and upload the **Daily Tracker Diary(ies)**, **CCSA-Caregiver survey**, **KCNT1 Demographics** and **Medications** surveys to the Study Coordinator via your Study Folder Link.

If you have questions, contact a Study Coordinator.

Months 2, 3, 4, & 5



Follow-Up Doctor Visit(s) & At-Home Monitoring

Continue to track daily symptoms! For all your follow-up doctor visits, repeat these steps at home and during the visit(s):

At-home, you will:

- Print **Daily Tracker Diary** (seizure and heart rate form) and complete for the first full week each time you are prescribed a new dose.

- Print and complete the **Parent Global Scale** every 30 days.

- Print enough copies of **Doctor Follow Up Packet B** to bring to each visit you have for the next 5 months*

**If your doctor discontinues the medication early, then skip to the final month (Month 6)!*

During Months 2 through 5, Study Coordinator(s) will reach out every 30 days to check-in and see if you need assistance entering any study forms!

- Every 30 days, please upload any scans/pictures of completed **Daily Tracker Diaries**, **Parent Global Scale**, and forms in the **Doctor Follow Up Packet B** surveys to your Study Folder Link.

If you have questions, contact a Study Coordinator.

During each follow-up appointment you will:

- Review with your doctor: all completed **Daily Tracker Diaries** & your monthly **Parent Global Scale**

- Jointly decide whether to change dose of carvedilol

- Your doctor should complete the form(s) in **Doctor Follow Up Packet B** during your appointment. Please collect the packet before you leave. If it's incomplete or you forget it, collect it from your doctor's office via email or mail.

Month 6 (or "Final Month")



Final Doctor Visit & At-Home Monitoring

Follow these steps when:

- *You've reached the maximum tolerated dose (are no longer increasing the dose), OR;*
- *You/your doctor decide to discontinue carvedilol, OR;*
- *You've reached Month 6.*

Print and complete the following surveys (from the website). Upload completed surveys to your Study Folder link:

- Parent Global Scale
- Re-take the CCSA-Caregiver survey
- Print the **Daily Tracker Diary** (seizure and heart rate form) and complete for any remaining week(s)
- Print a copy of **Doctor Final Packet C** to bring to your final visit

Go to your final follow-up doctor appointment. During the appointment:

- Review any completed **Daily Tracker Diary(ies)** & your monthly **Parent Global Scale** with your doctor
- Your doctor should complete the form(s) in **Doctor Final Packet C** during your appointment. Please collect the packet before you leave. If it's incomplete or you forget it, collect it from your doctor's office via email or mail.

Upload your completed forms to your Study Folder link

- Please upload any scans/pictures of completed **Daily Tracker Diaries** & **Doctor Follow Up Packet B** to your Study Folder Link.

Month 12 (Long Term Follow-Up)

- For longer-term analysis, you may also complete the following surveys again at 12 months and upload to your Study Folder Link: **Daily Tracker Diary** (1 Week), **Parent Global Scale** & **CCSA-Caregiver survey**.