

The CyNCh Study Data Archive

The Cysteamine Bitartrate Delayed-Release for the Treatment of Nonalcoholic Fatty Liver Disease (NAFLD) in Children (CyNCh) Archive contains the Protocol, Manual of Operations, Forms, Study Data, and Dataset Integrity Check.

The CyNCh study is a prospective, multicenter, double-blind clinical trial designed by the NASH Clinical Research Network to determine whether treatment with cysteamine improves disease severity in children diagnosed with NAFLD.

The current data package includes analysis data from a paper published by Schwimmer et al. in Gastroenterology in December 2016. The lock date for these datasets is January 3, 2016.

Archive files are organized into the following directories:

- Documents
- Forms
- Data
- Dataset Integrity Check (DSIC)
- SAS Programs

Documents

The CyNCh Documents directory contains:

- CyNCh_protocol.pdf – CyNCh Protocol
- CyNCh_SOPs.pdf – CyNCh Standard Operations Manual
- CyNCh_consentandassent.pdf – CyNCh parent informed consent, adolescent assent, and minor assent statements
- CyNCh_genetic_consentandassent.pdf – CyNCh parent informed consent and child assent statements for the use of samples in genetic research

Forms

The CyNCh Forms directory contains:

- CyNCh_Forms.pdf – Includes multiple forms for the CyNCh study, including:
 - Adverse Event Report (AE1)
 - Baseline History (BH1)
 - Central Histology Review (CR2)
 - Laboratory Results – Tests Done at Screening and Followup Visits (LR1)
 - Missed or Incomplete Visit (MV1)
 - Physical Examination (PE1)

- Focused Physical Examination (PF1)
- Pediatric Quality of Life: Parent Report for Teens (Age 13-17) (PQ1)
- Pediatric Quality of Life: Parent Report for Children (Age 8-12) (PR1)
- Pediatric Quality of Life: Child Report (Age 8-12) (PW1)
- Pediatric Quality of Life: Teen Report (Age 13-17) (PY1)
- Registration (RG1)
- Randomization Checks (RZ1, RZ2)

Data

The CyNCh data directory contains the following files, and the following analysis datasets in Windows-based SAS, v.7-8-9 format:

The datasets correspond to the tables in the Schwimmer paper. Note that the journal changed the order of Supplemental Tables 1 and 3. Therefore, the dataset and program for Supplemental Table 1 are named supptable3.sas7bdat and table_s3.sas. Similarly, the dataset and program for Supplemental Table 3 are named supptable1.sas7bdat and table_s1.sas.

- table1.sas7bdat
- table2.sas7bdat
- table3.sas7bdat
- table4.sas7bdat
- table5_all.sas7bdat
- table5_allsaes.sas7bdat
- table5_onerec.sas7bdat
- table5_onerecsaes.sas7bdat
- supptable1.sas7bdat
- supptable2.sas7bdat
- supptable3.sas7bdat
- figure1.sas7bdat
- supfig1.sas7bdat

Data\Contents

This subdirectory contains contents of data sets in the Data directory.

Data\SAS Output

This subdirectory contains means, frequencies, and generalized linear models of data sets in the Data directory

DSIC

The CyNCh Data Integrity Check (DSIC) directory contains:

- CyNCh_DSIC.pdf - A report of an examination of the Table1, Table2, Table 3, Table 4, and Table 5 datasets (Schwimmer paper) for completeness by statisticians and quality control specialists at the Repository. Published results from the CyNCh data were compared to values recalculated from CyNCh archived analysis datasets in the NIDDK repository.

SAS Programs

This subdirectory contains the SAS programs which created the analysis data sets in the Data directory.