

Losartan for the Treatment of Pediatric Nonalcoholic Fatty Liver Disease (STOP-NAFLD) Study Data Archive

The STOP-NAFLD trial was a multicenter, double-masked, placebo-controlled, randomized phase 2 trial to determine whether treatment with losartan improves measures of nonalcoholic fatty liver disease (NAFLD) in children. Children between the ages of 8 and 17 years with biopsy-proven NAFLD were eligible for the study. Participants were enrolled and randomized to treatment with either 100 mg of losartan or matching placebo orally once daily for 24 weeks. Improvement in NAFLD at 24 weeks, defined as a decrease in serum alanine aminotransferase (ALT), was assessed as the primary outcome measure. Secondary outcome measures, also assessed at 24 weeks, included relative change in ALT; changes in serum aspartate aminotransferase (AST) and gamma-glutamyl transpeptidase (GGT); change in Homeostatic Model Assessment of Insulin Resistance (HOMA-IR); changes in anthropometric measurements, BMI z-score, and serum lipid profiles; and self-reported quality of life.

Archive files are organized into the following directories:

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

Data

The STOP-NAFLD Data directory contains the following datasets in SAS and CSV formats:

- etable1
- figure1a
- figure1b
- figure2
- table1
- table2
- table3
- table4
- table5

Data/Contents:

- STOP_NAFLD_Proc_Contents.pdf

Documents

The STOP-NAFLD Documents directory contains:

- STOP-NAFLD_Hepatology_2022.pdf
- STOP-NAFLD_protocol.pdf

- STOP-NAFLD_SOPs.pdf
- STOP_NAFLD_Hepatology_2022_SupplTable1.pdf

DSIC

The STOP-NAFLD DSIC directory contains:

- STOP-NAFLD_DSIC.pdf

Forms

The STOP-NAFLD Forms directory contains:

- STOP-NAFLD_forms.pdf

SAS Programs

The STOP-NAFLD SAS Programs directory contains:

- etable1.sas
- figure1a.sas
- figure1b.sas
- figure2.sas
- table1.sas
- table2.sas
- table3.sas
- table4.sas
- table5.sas