

The RISE Pediatric Medication Study Data Archive

The RISE Pediatric Medication Study was a two-arm, multi-center clinical trial. Study participants were enrolled at four recruitment centers and randomized into two treatment groups. The first group received metformin alone for 12 months. The second group received glargine, a man-made insulin, for three months followed by metformin for the remaining nine months of the treatment period. Beta-cell function and insulin sensitivity were assessed at baseline, the end of the active treatment period, and three months after treatment was withdrawn.

Archive files are organized into the following directories:

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

Documents

The RISE Pediatric Documents directory contains:

- Documentation for RISE Pediatric data release FINAL.pdf

Forms

The RISE Pediatric Forms directory contains:

- BASELINE_Baseline Visit Inventory.pdf
- CLAMP_clamp procedures.pdf
- EXITFORM Participant end-of-study exit interview.pdf
- HISTORY Participant history
- LOCLAB Local lab results.pdf
- OGTT_OGTT procedures.pdf
- Pediatric sleep questionnaires.pdf
- RUNEND Run-in end inventory.pdf
- RUNSTART Run-in start inventory.pdf
- SCREEN Screening Inventory.pdf
- SMBG Self monitoring blood glucose.pdf
- VISIT Post randomization visit inventory.pdf

Data

The RISE Pediatric data directory contains the following files, and the following datasets in Windows-based SAS, v. 7-8-9 format. Each dataset corresponds to the form of the same name:

- risepeds_basedata
- risepeds_baseline
- risepeds_clampdata
- risepeds_clamp
- risepeds_exitform
- risepeds_history
- risepeds_loclab
- risepeds_ogttdata
- risepeds_ogtt
- risepeds_otherlabdata
- risepeds_runend
- risepeds_runstart
- risepeds_screendata
- risepeds_screen
- risepeds_slpq_ped
- risepeds_smbg
- risepeds_status
- risepeds_unsched
- risepeds_visit

Data/Contents

- Pediatric sleep questionnaires - Data dictionary.pdf
- RISEPeds_basedata.rtf
- RISEPeds_baseline.rtf
- RISEPeds_ClampData.rtf
- RISEPeds_clamp.rtf
- RISEPeds_exitform.rtf
- RISEPeds_history.rtf
- RISEPeds_LOCLAB.rtf
- RISEPeds_OGTTData.rtf
- RISEPeds_OGTT.rtf
- RISEPeds_OtherLabData.rtf
- RISEPeds_runend.rtf
- RISEPeds_runstart.rtf
- RISEPeds_screen.rtf
- RISEPeds_SLPQ_PED.rtf
- RISEPeds_SMBG.rtf
- RISEPeds_STATUS.rtf
- RISEPeds_unsched.rtf

- RISEPeds_visit.rtf

DSIC

The RISE Pediatric Data Integrity Check (DSIC) directory contains:

- RISE_Pediatric_DSIC_V1.pdf - A report of an examination of the analysis and form datasets for completeness by statisticians and quality control specialists at the Repository. Reported results from the RISE Pediatric data were compared to values recalculated from RISE Pediatric archived analysis datasets in the NIDDK repository.