

A Multicenter Clinical Trial of Allopurinol to Prevent GFR Loss in Type 1 Diabetes (PERL) Study Data Archive

Despite improvements during the past 20 years in blood glucose and blood pressure control, diabetic kidney disease remains one of the leading causes of health problems in patients with diabetes. Novel treatments to complement blood glucose and blood pressure control are urgently needed. The goal of this study was to see whether a medication called allopurinol may help prevent loss of kidney function among people with type 1 diabetes (T1D). Allopurinol has been used for many years to decrease high blood uric acid and treat gout. There is evidence suggesting that allopurinol might also be useful in people with diabetes who have normal or moderately impaired kidney function to decrease the risk of developing advanced kidney disease in the future. To prove this beneficial effect of allopurinol, a double-blinded, international clinical trial was conducted with patients with T1D that had an increased risk of developing kidney disease. Participants were randomly assigned to take allopurinol or placebo (inactive pill) for three years, during which they were followed through periodical visits. Kidney function was measured at the beginning and at the end of the treatment period to assess whether patients taking allopurinol experienced a slower loss of kidney function over time compared to those taking the inactive pill.

Archive files are organized into the following directories:

- Data
- Documents
- Dataset Integrity Check (DSIC)

Data

The PERL Data directory contains the following datasets:

Data/Analytical Data

- Data_contents_Analytical_Data.xlsx
- Data_Statistics_perl_baseline.xlsx
- Data_Statistics_perl_disposition.xlsx
- Data_Statistics_perl_visit.xlsx
- Data_Statistics_safety_ae.xlsx
- Data_Statistics_safety_sae.xlsx
- Data_Statistics_secondary_outcome.xlsx
- PERL_BASELINE.CSV
- perl_baseline.sas7bdat
- PERL_DISPOSITION.CSV
- perl_disposition.sas7bdat
- PERL_VISIT.CSV
- perl_visit.sas7bdat
- SAFETY_AE.CSV
- safety_ae.sas7bdat
- SAFETY_SAE.CSV
- safety_sae.sas7bdat
- SECONDARY_OUTCOME.CSV
- secondary_outcome.sas7bdat

Data/Form Data

- Data_Contents_PERL_Forms_2021_02_12.xlsx
- Data_Statistics_oc_form_001r.xlsx
- Data_Statistics_oc_form_001s.xlsx
- Data_Statistics_oc_form_002.xlsx
- Data_Statistics_oc_form_006.xlsx
- Data_Statistics_oc_form_007.xlsx
- Data_Statistics_oc_form_008.xlsx
- Data_Statistics_oc_form_009.xlsx
- Data_Statistics_oc_form_011.xlsx
- Data_Statistics_oc_form_012.xlsx
- Data_Statistics_oc_form_013.xlsx
- Data_Statistics_oc_form_014b.xlsx
- Data_Statistics_oc_form_014c.xlsx
- Data_Statistics_oc_form_014mfg.xlsx
- Data_Statistics_oc_form_015.xlsx
- Data_Statistics_oc_form_016.xlsx
- Data_Statistics_oc_form_019.xlsx
- Data_Statistics_oc_form_022.xlsx
- Data_Statistics_oc_form_023f.xlsx
- Data_Statistics_oc_form_023i.xlsx
- Data_Statistics_oc_form_026.xlsx
- Data_Statistics_oc_form_035.xlsx
- Data_Statistics_oc_form_040.xlsx
- OC_FORM_001.CSV
- oc_form_001.sas7bdat
- OC_FORM_001R.CSV
- oc_form_001r.sas7bdat
- OC_FORM_001S.CSV
- oc_form_001s.sas7bdat
- OC_FORM_002.CSV
- oc_form_002.sas7bdat
- OC_FORM_006.CSV
- oc_form_006.sas7bdat
- OC_FORM_007.CSV
- oc_form_007.sas7bdat
- OC_FORM_008.CSV
- oc_form_008.sas7bdat
- OC_FORM_009.CSV
- oc_form_009.sas7bdat
- OC_FORM_011.CSV
- oc_form_011.sas7bdat
- OC_FORM_012.CSV
- oc_form_012.sas7bdat

- OC_FORM_013.CSV
- oc_form_013.sas7bdat
- OC_FORM_014B.CSV
- oc_form_014b.sas7bdat
- OC_FORM_014C.CSV
- oc_form_014c.sas7bdat
- OC_FORM_014MFG.CSV
- oc_form_014mfg.sas7bdat
- OC_FORM_015.CSV
- oc_form_015.sas7bdat
- OC_FORM_016.CSV
- oc_form_016.sas7bdat
- OC_FORM_019.CSV
- oc_form_019.sas7bdat
- OC_FORM_022.CSV
- oc_form_022.sas7bdat
- OC_FORM_023F.CSV
- oc_form_023f.sas7bdat
- OC_FORM_023I.CSV
- oc_form_023i.sas7bdat
- OC_FORM_026.CSV
- oc_form_026.sas7bdat
- OC_FORM_035.CSV
- oc_form_035.sas7bdat
- OC_FORM_040.CSV
- oc_form_040.sas7bdat

Data/Study Lab Results Data

- CENTRAL_LAB_DATA.CSV
- central_lab_data_2021_02_12.sas7bdat
- Data_Statistics_central_lab_data-2021-02.xlsx
- PERL_CLAB_data dictionary.xlsx

Documents

The PERL Documents directory contains:

- Instructions for PERL Data.pdf
- MOO.pdf
- PERL Version_10.0_(PDF_document)_03_06_2018.pdf
- PERL_Derived_Variables_Formula.pdf

Documents/Bibliography

- Key Study Publication.pdf
- PERL_Baseline_Paper.pdf

Documents/Codebook

- PERL Casebook and Forms 07AUG2018.pdf

DSIC

The PERL DSIC directory contains:

- PERL_DSIC_V1.pdf