

Antithymocyte Globulin (ATG) and Pegylated Granulocyte Colony Stimulating Factor (GCSF) in New Onset Type 1 Diabetes (TN19) Study Data Archive

The TrialNet 19 (TN19) study was a three-arm, 1:1:1 randomized, placebo controlled, double-blinded trial in which participants either received active antithymocyte globulin (ATG) and granulocyte colony stimulating factor (GCSF), received ATG alone, or received a placebo alone within 100 days from diagnosis of type 1 diabetes. TrialNet researchers assessed whether ATG used alone or in combination with GCSF helped participants continue to make some of their own insulin.

The study had a treatment phase and a follow-up phase. The treatment phase was during the first 3 months of the study. During this time, participants had one inpatient stay for 3 days and 2 nights to receive two infusions of low dose ATG or placebo followed by one injection of GCSF or placebo. Participants returned for five additional outpatient visits over the next 10 weeks (every 2 weeks) to receive an injection of GCSF or placebo. After the treatment phase, participants moved to the follow-up phase and returned for outpatient visits every 3 to 6 months. The study had a total participation time of two years.

Archive files are organized into the following directories:

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

Data

The TN19 Data directory contains:

Data/Analysis Datasets/Primary

- AE.CSV
- ae.sas7bdat
- AUTOAB.CSV
- autoab.sas7bdat
- BMI.CSV
- bmi.sas7bdat
- CBC.CSV
- cbc.sas7bdat
- CD4CD8.CSV
- cd4cd8.sas7bdat
- CD4CD8X.CSV
- cd4cd8x.sas7bdat
- CHANGE.CSV
- change.sas7bdat
- CPEPTIDE.CSV
- cpeptide.sas7bdat
- HBA1C.CSV

- hba1c.sas7bdat
- HYPO.CSV
- hypo.sas7bdat
- INSULIN.CSV
- insulin.sas7bdat
- MASTABLE.CSV
- mastable.sas7bdat
- MMTT.CSV
- mmtt.sas7bdat
- TREATMENT.CSV
- treatment.sas7bdat

Data/Analysis Datasets/Secondary/TN ASID-069 ImmunoChip

- readme_TN ASID-069 ImmunoChip.txt
- TN ASID-069 ImmunoChip Mapping List.xlsx
- trialnet_hg19_EUR.bed
- trialnet_hg19_EUR.bim
- trialnet_hg19_EUR.fam
- trialnet_hg19_EUR_Rel.bed
- trialnet_hg19_EUR_Rel.bim
- trialnet_hg19_EUR_Rel.fam
- trialnet_hg19_Extra.bed
- trialnet_hg19_Extra.bim
- trialnet_hg19_Extra.fam

Data/Analysis Datasets/TN19 Flow Analysis Dataset

- TN19 RAGE APC Data.xlsx
- TN19 RAGE Sample List.xlsx
- TN19 RAGE X-TRIAL Data.xlsx

Data/Final Datasets

- TN19_ADVERSEEVENTS.CSV
- tn19_adverseevents.sas7bdat
- TN19_BASELINEELIGIBILITY.CSV
- tn19_baselineeligibility.sas7bdat
- TN19_BASELINEVISITASSESSMENT.CSV
- tn19_baselinevisitassessment.sas7bdat
- TN19_CBCDIFFERENTIAL.CSV
- tn19_cbcifferential.sas7bdat
- TN19_CD4CD8RATIORESULTS.CSV
- tn19_cd4cd8ratioresults.sas7bdat
- TN19_CHANGEINSTUDYDRUG.CSV
- tn19_changeinstudydrug.sas7bdat
- TN19_CHANGEOFSTATUS.CSV

- tn19_changeofstatus.sas7bdat
- TN19_CONCOMITANTMEDS.CSV
- tn19_concomitantmeds.sas7bdat
- TN19_DIABETESMANAGEMENT.CSV
- tn19_diabetesmanagement.sas7bdat
- TN19_EBVPCRVLOCALLABRESULTS.CSV
- tn19_ebvpcrvlocallabresults.sas7bdat
- TN19_FLUADMINISTRATION.CSV
- tn19_fluadministration.sas7bdat
- TN19_FOLLOWUPELIGPARTICIPANT.CSV
- tn19_followupeligparticipant.sas7bdat
- TN19_FOLLOWUPELIGPARTICIPANT2.CSV
- tn19_followupeligparticipant2.sas7bdat
- TN19_PARTICIPANTSITETRANSFER.CSV
- tn19_participantsitetransfer.sas7bdat
- TN19_PREGNANCYCONFIRMATION.CSV
- tn19_pregnancyconfirmation.sas7bdat
- TN19_PROTOCOLDEVIATION.CSV
- tn19_protocoldeviation.sas7bdat
- TN19_REGISTRATION.CSV
- tn19_registration.sas7bdat
- TN19_RESEARCHLABS.CSV
- tn19_researchlabs.sas7bdat
- TN19_SCREENINGELIGIBILITY.CSV
- tn19_screeningeligibility.sas7bdat
- TN19_SCREENINGVISITASSESSMENT.CSV
- tn19_screeningvisitassessment.sas7bdat
- TN19_STUDYDRUGADMINISTRATION.CSV
- tn19_studydrugadministration.sas7bdat
- TN19_TREATMENTSTARTDATE.CSV
- tn19_treatmentstartdate.sas7bdat
- TN19_URINALYSISEVALUATION.CSV
- tn19_urinalysisevaluation.sas7bdat
- TN19_VISITASSESSMENT.CSV
- tn19_visitassessment.sas7bdat

Documents

The TN19 Documents directory contains:

- Manual_of_Operations.pdf
- Protocol.pdf

Documents/TN19 Flow Analysis Documents

- RAGE APC Summary Report_AnalysisDataset.pdf

- RAGE_Tfh Summary Report_AnalysisDataset.pdf
- TN19 RAGE Sample List. Data Dictionary.pdf

DSIC

The TN19 Dataset Integrity Check (DSIC) directory contains:

- DSIC.doc
- TN19_DSIC_Final.pdf

Forms

The TN19 Forms directory contains:

- 01 Screening Eligibility Form 20150108.docx
- 02 Screening Visit Assessment Form 20141212.docx
- 03 Concomitant Medications Form 20140509.doc
- 04 CBC with Differential Results Form 20140512.docx
- 05 Urinalysis Evaluation Form 20140512.docx
- 06 Baseline Eligibility Form 20140603.docx
- 07 Baseline Visit Assessment Form 20141212.docx
- 08 Diabetes Management Form 20150529.doc
- 09 Treatment Start Date Form 20140522.docx
- 10 Visit Assessment Form 20141212.docx
- 11 Study Drug Administration 20141212.doc
- 12 Protocol Deviation Form 20140709.docx
- 13 Participant Site Transfer Form 20140715.docx
- 14 Change in Study Status Form 20140714.doc
- 15 Change in Study Drug Form 20140522.doc
- 16 Pregnancy Confirmation Form 20140512.docx
- 17 Pregnancy Outcome Report Form 20140702.docx
- 18 Mortality Event Form 20140512.doc
- 20 TN19 ATG-GCSF Interim Phone Contact Form.docx
- 22 CD4 CD8 Ratio Results Local Lab Form 20150512 V2.docx
- 22 EBV PCR_Viral Load_Results Local Lab Form 20150512.docx
- 23 EBV PCR_Viral Load_Results Local Lab Form 20150512 V2.docx