

The TrialNet 07 (TN07) Study Data Archive

The Oral Insulin for Prevention of Diabetes in Relatives at Risk for Type 1 Diabetes Mellitus

(TN07) study was a triple masked randomized controlled trial assessing the impact of oral insulin on progression to type 1 diabetes among study participants.

Archive files are organized into the following directories:

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

Data

The TN07 Data directory contains the following datasets in Windows-based SAS and CSV files:

- AE.CSV
- ae.sas7bdat
- AUTOAB.CSV
- autoab.sas7bdat
- BMI.CSV
- bmi.sas7bdat
- CPEPM.CSV
- cpepm.sas7bdat
- CPEPO.CSV
- cpepo.sas7bdat
- GTT.CSV
- gtt.sas7bdat
- HBA1C.CSV
- hba1c.sas7bdat
- HLA.CSV
- hla.sas7bdat
- INSULIN.CSV
- insulin.sas7bdat
- MASTABLE.CSV
- mastable.sas7bdat
- REL.CSV
- rel.sas7bdat
- RX.CSV
- rx.sas7bdat
- TN07_3MONTHVISIT.CSV
- tn07_3monthvisit.sas7bdat
- TN07_6MONTHVISIT.CSV
- tn07_6monthvisit.sas7bdat
- TN07_ADDITIONALCONSENT.CSV
- tn07_additionalconsent.sas7bdat
- TN07_ADVERSEEVENTS.CSV

- tn07_adverseevents.sas7bdat
- TN07_ADVERSEEVENTSREVIEW.CSV
- tn07_adverseeventsreview.sas7bdat
- TN07_ANNUALVISIT.CSV
- tn07_annualvisit.sas7bdat
- TN07_CHANGEINSTATUS.CSV
- tn07_changeinstatus.sas7bdat
- TN07_CHANGEINSTUDYDRUG.CSV
- tn07_changeinstudydrug.sas7bdat
- TN07_CONCOMITANTMEDS.CSV
- tn07_concomitantmeds.sas7bdat
- TN07_DIABETESONSET.CSV
- tn07_diabetesonset.sas7bdat
- TN07_ELIGIBILITY.CSV
- tn07_eligibility.sas7bdat
- TN07_FOLLOWUPDRUGALLOCATION.CSV
- tn07_followupdrugallocation.sas7bdat
- TN07_H1N1VACCINATION.CSV
- tn07_h1n1vaccination.sas7bdat
- TN07_INITIALVISIT.CSV
- tn07_initialvisit.sas7bdat
- TN07_PERMANENTSITETRANSFER.CSV
- tn07_permanentsitetransfer.sas7bdat
- TN07_PHONECONTACT.CSV
- tn07_phonecontact.sas7bdat
- TN07_PREGNANCYCONFIRMATION.CSV
- tn07_pregnancyconfirmation.sas7bdat
- TN07_PREGNANCYOUTCOME.CSV
- tn07_pregnancyoutcome.sas7bdat
- TN07_PROTOCOLDEVIATION.CSV
- tn07_protocoldeviation.sas7bdat
- TN07_REGISTRATION.CSV
- tn07_registration.sas7bdat
- TN07_RESEARCHLABS.CSV
- tn07_researchlabs.sas7bdat
- TN07_STUDYDRUG.CSV
- tn07_studydrug.sas7bdat
- TN07_STUDYENDPOINTVISIT.CSV
- tn07_studyendpointvisit.sas7bdat
- TN07_TREATMENTSTARTDATE.CSV
- tn07_treatmentstartdate.sas7bdat

Documents

The TN07 Documents directory contains the following files and subdirectory:

- 01 TN07 Oral Insulin Study Protocol 01Nov12.pdf

Documents/MOO

- 03 TN07 Protocol MOO FINAL Version 6 0 25Feb15.pdf
- Appendix A. Progression from TN01 to TN07.pdf
- Appendix B. Proband Definition.pdf
- Appendix C. Reimbursement.pdf
- Appendix D. Summary of Visit Windows.pdf
- Appendix E. Intravenous Glucose Tolerance Test (IVGTT).pdf
- Appendix F. Oral Glucose Tolerance Test (OGTT).pdf
- Appendix G. Participant Drug Information Sheet.pdf
- Appendix H. Tanner Stages.pdf
- Appendix I. Protocol Deviation Checklist.pdf
- Appendix J. TN07 Oral Insulin Training Materials Reference Tool.pdf
- Appendix K. Definitions.pdf
- Appendix L. Study Summary.pdf
- Appendix M. TN07 OI Memo to Clarify Serious Adverse Event Reporting 04Aug10.pdf

DSIC

The TN07 Dataset Integrity Check (DSIC) directory contains:

- TN07_DSIC.pdf
- TrialNet_07_integrity_check.pdf

Forms

- Adverse Event Reporting Form.pdf
- Change of Status.pdf
- Concomitant Medications.pdf
- Diabetes Onset.pdf
- FOLLOW-UP OF ELIGIBLE PARTICIPANT.pdf
- H1N1 Vaccination Form.pdf
- Mortality Event.pdf
- OT01 - Initial Visit.pdf
- OT02 - Eligibility.pdf
- OT03 - 3 Month Follow-Up Visit.pdf
- OT04 - Semi-Annual Follow-Up Visit.pdf
- OT05 - Annual Follow-Up Visit.pdf
- OT06 - 3 Month Interim Phone Contact.pdf
- OT07 - Change in Study Drug.pdf
- OT14 - Study Drug Dispensation and Return.pdf
- OT18 STUDY ENDPOINT VISIT STATUS AND TRACKING.pdf
- OT19 - FOLLOW-UP VISIT DRUG ALLOCATION FORM.pdf
- Permanent Participant Site Transfer.pdf
- Pregnancy Confirmation.pdf
- Pregnancy Outcome Report.pdf
- Protocol Deviation.pdf
- Treatment Start Date.pdf