DATE CREATED: Jun28,2025
Number of Observations: 119
Number of Variables: 42

| **FileName** | **Variable\_label** | **Variable\_Name** | **Category** | **N\_\_Percent** | **Mean\_\_SD** | **Median\_Q1\_Q3** | **Range** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| inex | Blind\_id | Blind\_id |  | 119(100) |  |  |  |
| inex | Blinded\_SiteID | Blinded\_SiteID |  | 119(100) |  |  |  |
| inex | Visit Name | VISNAME | Screening | 119(100) |  |  |  |
| inex | A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)? | AGE\_categorie | (Empty string) | 100(84) |  |  |  |
| inex | A1. Is the subject aged 10 to 17 years (with 2 year availability for study participation)? | AGE\_categorie | Yes | 19(16) |  |  |  |
| inex | A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)? | BMI\_categorie | (Empty string) | 100(84) |  |  |  |
| inex | A2. Is the BMI ≥ 95th percentile (using CDC BMI charts)? | BMI\_categorie | Yes | 19(16) |  |  |  |
| inex | A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥100 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥145 mg/dL | FLP1 | (Empty string) | 100(84) |  |  |  |
| inex | A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥100 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 3.0 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥145 mg/dL | FLP1 | Yes | 19(16) |  |  |  |
| inex | A4. Participant consent, or parental/guardian consent and participant assent obtained | FLP1\_IC | Yes | 119(100) |  |  |  |
| inex | A5. Is the subject fluent in English? | ENGLISH | (Empty string) | 100(84) |  |  |  |
| inex | A5. Is the subject fluent in English? | ENGLISH | Yes | 19(16) |  |  |  |
| inex | <b>Inclusion Criteria met?</b> | INCL\_MET | 1 | 119(100) |  |  |  |
| inex | B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretin | MEDS | (Empty string) | 15(12.6) |  |  |  |
| inex | B1. Current use of lipid lowering medication, antihypertensive medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretin | MEDS | No | 104(87.4) |  |  |  |
| inex | B2. Known allergy or hypersensitivity to statin | ALLERGY | No | 119(100) |  |  |  |
| inex | B3. Female who is pregnant, plans to become pregnant or is sexually active without contraception | PREG | No | 119(100) |  |  |  |
| inex | B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for subjects <13 years of age; ≥140/90 for subjects ≥13 years of age) confirmed after an a | HYPERT | (Empty string) | 15(12.6) |  |  |  |
| inex | B4. Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for subjects <13 years of age; ≥140/90 for subjects ≥13 years of age) confirmed after an a | HYPERT | No | 104(87.4) |  |  |  |
| inex | B5. Diabetes (type 1 or type 2) by American Diabetes Association criteria (fasting glucose ≥126 mg/dL, HbA1c ≥ 6.5%, random glucose ≥ 200 mg/dL, or 2-hour oral glucose tolerance testing glucose ≥ 200 mg/dL) | DIABETES | No | 119(100) |  |  |  |
| inex | B6. Use of insulin sensitizing therapy | PD\_PCS | No | 119(100) |  |  |  |
| inex | B7. Known renal insufficiency (known chronic renal disease, estimated GFR <60 mL/min/1.73m2 at screening) | RENAL | No | 119(100) |  |  |  |
| inex | B8. Uncontrolled thyroid disease (TSH at screening >1.5x upper limit of normal, clinical of other laboratory evidence of hypothyroidism, or thyroid hormone therapy that has not been stable for 6 weeks prior to screening) | THYROID | No | 119(100) |  |  |  |
| inex | B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2) | PROTEIN | (Empty string) | 100(84) |  |  |  |
| inex | B9. Proteinuria suggestive of renal disease (urine protein: creatinine >0.2) | PROTEIN | No | 19(16) |  |  |  |
| inex | B10. Syndromic patients or patients with neurocognitive delay precluding adherence with study drug | NEURO | No | 119(100) |  |  |  |
| inex | B11. Liver disease other than non-alcoholic fatty liver disease (NAFLD) either diagnosed or suggested by alanine amiotransferase (ALT) ≥ 40 U/L, or severe NAFLD indicated by ALT ≥ 200 U/L | LIVER | No | 119(100) |  |  |  |
| inex | B12. Unexplained persistent elevated creatine kinase (CK) level >3x upper limit of normal | CREATINE | No | 119(100) |  |  |  |
| inex | B13. Plans to leave the geographic area before completion of the anticipated 2 years of trial participation | LEAVE | No | 119(100) |  |  |  |
| inex | B14. Any unstable medical or emotional condition or chronic disease that would preclude following the protocol or impact valid vascular measurement | UNSTABLE | No | 119(100) |  |  |  |
| inex | B15. Admits to current smoking, current alcohol consumption | FLP1\_SMOK | No | 119(100) |  |  |  |
| inex | <b>Exclusion Criteria met?</b> | EXCL\_MET | 0 | 119(100) |  |  |  |
| inex | <b>Is subject eligible for Randomization?</b> | ENROLL\_YN | 1 | 119(100) |  |  |  |
| inex | A1. Is the subject aged 10 to 18 years (with 2 year availability for study participation)? | AGE\_5V | (Empty string) | 34(28.6) |  |  |  |
| inex | A1. Is the subject aged 10 to 18 years (with 2 year availability for study participation)? | AGE\_5V | Yes | 85(71.4) |  |  |  |
| inex | A2. Is the BMI ≥ 85th percentile (using CDC BMI charts)? | BMI\_5V | (Empty string) | 19(16) |  |  |  |
| inex | A2. Is the BMI ≥ 85th percentile (using CDC BMI charts)? | BMI\_5V | Yes | 100(84) |  |  |  |
| inex | A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥90 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥125 mg/dL | FLP1\_5V | (Empty string) | 34(28.6) |  |  |  |
| inex | A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥90 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥125 mg/dL | FLP1\_5V | No | 1(0.8) |  |  |  |
| inex | A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥90 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥125 mg/dL | FLP1\_5V | Yes | 84(70.6) |  |  |  |
| inex | B16. Patients who have had bariatric surgery or plan to have bariatric surgery during the trial | BARISURG | (Empty string) | 19(16) |  |  |  |
| inex | B16. Patients who have had bariatric surgery or plan to have bariatric surgery during the trial | BARISURG | No | 100(84) |  |  |  |
| inex | B9. Proteinuria suggestive of renal disease (more than trace together with an elevated urine protein:creatinine ratio as per local lab) | PROTEIN\_5V | (Empty string) | 19(16) |  |  |  |
| inex | B9. Proteinuria suggestive of renal disease (more than trace together with an elevated urine protein:creatinine ratio as per local lab) | PROTEIN\_5V | No | 100(84) |  |  |  |
| inex | D1. Did participant complete a Re-Screening Visit? | RESCRN\_YN | (Empty string) | 13(10.9) |  |  |  |
| inex | D1. Did participant complete a Re-Screening Visit? | RESCRN\_YN | No | 96(80.7) |  |  |  |
| inex | D1. Did participant complete a Re-Screening Visit? | RESCRN\_YN | Yes | 10(8.4) |  |  |  |
| inex | D3. Does participant still meet all non-lab-related exclusion per protocol? | EXCLPROT | (Empty string) | 109(91.6) |  |  |  |
| inex | D3. Does participant still meet all non-lab-related exclusion per protocol? | EXCLPROT | Yes | 10(8.4) |  |  |  |
| inex | D3a. If no, select the exclusion criteria no longer met | EXCL | (Empty string) | 119(100) |  |  |  |
| inex | D4. Does participant still meet BMI per protocol (Inclusion criteria except age/FLP)? | BMIFLX | (Empty string) | 109(91.6) |  |  |  |
| inex | D4. Does participant still meet BMI per protocol (Inclusion criteria except age/FLP)? | BMIFLX | Yes | 10(8.4) |  |  |  |
| inex | D5. Was a second set of screening FLP drawn? | SECFLP | (Empty string) | 109(91.6) |  |  |  |
| inex | D5. Was a second set of screening FLP drawn? | SECFLP | No | 1(0.8) |  |  |  |
| inex | D5. Was a second set of screening FLP drawn? | SECFLP | Yes | 9(7.6) |  |  |  |
| inex | D5a. Does participant have a second screening FLP that meets the current protocol's criteria or the 10% flex FLP criteria (specified below)? | SECFLPCR | (Empty string) | 110(92.4) |  |  |  |
| inex | D5a. Does participant have a second screening FLP that meets the current protocol's criteria or the 10% flex FLP criteria (specified below)? | SECFLPCR | Yes, second FLP meets 10% flex criteria | 1(0.8) |  |  |  |
| inex | D5a. Does participant have a second screening FLP that meets the current protocol's criteria or the 10% flex FLP criteria (specified below)? | SECFLPCR | Yes, second FLP meets original ranges specified in current protocol | 8(6.7) |  |  |  |
| inex | A1. Is the subject aged 10 to 19 years (with 2 year availability for study participation)? | AGE\_7V | (Empty string) | 104(87.4) |  |  |  |
| inex | A1. Is the subject aged 10 to 19 years (with 2 year availability for study participation)? | AGE\_7V | Yes | 15(12.6) |  |  |  |
| inex | A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥90 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥120 mg/dL | FLP1\_7V | (Empty string) | 104(87.4) |  |  |  |
| inex | A3. Fasting lipid profile x2 each with all of the following: • LDL-C <160 mg/dL and ≥90 mg/dL, and • TG <500 mg/dL, and • TG/HDL-C ratio ≥ 2.5 or HDL-C <45 mg/dL for boys or HDL-C <50 mg/dL for girls, and • non-HDL-C ≥120 mg/dL | FLP1\_7V | Yes | 15(12.6) |  |  |  |
| inex | B1. Current use of lipid lowering medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulan | MEDS\_7V | (Empty string) | 104(87.4) |  |  |  |
| inex | B1. Current use of lipid lowering medication, growth hormone, systemic corticosteroids, cyclosporine, protease inhibitors, erythromycin, rifampin, colchicine, warfarin, second generation psychotropic drugs, oral isotretinoin; stable doses of stimulan | MEDS\_7V | No | 15(12.6) |  |  |  |
| inex | B4. Uncontrolled Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) | HYPERT\_7V | (Empty string) | 104(87.4) |  |  |  |
| inex | B4. Uncontrolled Stage 2 hypertension (systolic or diastolic blood pressure ≥ 95th percentile for age, sex and height percentile + 12 mmHg or ≥140/90, whichever is lower for participants <13 years of age; ≥140/90 for participants ≥13 years of age) | HYPERT\_7V | No | 15(12.6) |  |  |  |
| inex | D2. Age at Rescreening Date | RESCRN\_Age |  | 10(8) | 14.1(2.4) | 13.41(12.49,15.43) | 11.11,18.19 |