**ONLINE APPENDIX**

**Table 1. Characteristics of those included and excluded (outside 1 year window) for DPT-1 analysis**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Included (n=282)** | **Excluded\* (n=87)** | **p-values** |
| **Age (yrs)** | **12.5±8.6** | **12.6±8.4** | **0.971** |
| **Body Mass Index (kg/m2)** | **20.7±8.2** | **19.8±4.7** | **0.342** |
| **Gender (% Female)** | **38.7** | **44.8** | **0.304** |
| **DPTRS** | **6.4±0.8** | **6.4±1.0** | **0.947** |
| **AUC Glucose (mg/dl)/120 min** | **118.5±18.3** | **120.0±21.03** | **0.881** |
| **AUC C-peptide (ng/ml)/120 min** | **4.0±1.6** | **4.1±1.7** | **0.530** |

**\*3 with missing values not included in table**

**Table 2. Characteristics of those included and excluded (outside 1 year window) for TrialNet analysis**

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|  |
|  | **Study Subjects****(n=340)** | **Excluded****(n=41)** | **p-values** |
| **Age (yrs)** | **9.4±5.6** | **11.4±8.4** | **0.146** |
| **Body Mass Index (kg/m2)** | **18.2±4.1** | **19.2±4.6** | **0.124** |
| **Gender (% Female)** | **37.4** | **41.5** | **0.608** |
| **DPTRS** | **6.4±0.8** | **6.3±0.9** | **0.643** |
| **AUC Glucose (mg/dl)/120 min** | **122.8±16.2** | **122.1±16.7** | **0.792** |
| **AUC C-peptide (ng/ml)/120 min** | **4.7±2.1** | **4.8±2.0** | **0.668** |
| **30-0 minute C-peptide (ng/ml)** | **3.3±1.9** | **3.6±2.1** | **0.280** |

**Table 3. AUC Ratio (mean±SD) after 1 year for DPTRS≥6.75**

|  |  |
| --- | --- |
|  | **AUC Ratio [(ng/ml)/(mg/dl)]x100** |
| **Oral Insulin** | **Placebo** |
| **DPT-1****Placebo: n=53 Oral Insulin n=37** | **2.86±1.06+** | **2.42±1.03** |
| **TrialNet Placebo: n=58 Oral Insulin: n=60** | **3.06±1.13+\*** | **2.57±0.96** |

**+p<0.05 (baseline adjusted) for comparison with placebo group +\*p=0.057 with age adjustment (p-values<0.05 with DPTRS adjustment)**

**Table 4. Characteristics of oral insulin and placebo groups among high risk DPT-1 participants**

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|  | **Oral Insulin****(n=37)** | **Placebo****(n=53)** | **p-values** |
| **Age (yrs)** | **9.8±5.8** | **7.9±3.8** | **0.089** |
| **Log Body Mass Index** | **3.0±0.2** | **3.0±0.4** | **0.643** |
| **Gender (% Female)** | **37.8** | **45.3** | **0.482** |
| **DPTRS** | **7.1±0.3** | **7.3±0.5** | **0.072** |
| **Index60** | **0.9±0.4** | **0.8±0.5** | **0.586** |
| **AUC Glucose (mg/dl)/120 min** | **130.7±14.2** | **132.7±13.8** | **0.495** |
| **AUC C-peptide (ng/ml)/120 min** | **3.3±1.1** | **3.4±1.2** | **0.655** |

**Table 5. Characteristics of oral insulin and placebo groups among high risk TrialNet participants**

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|  | **Oral Insulin****(n=60)** | **Placebo****(n=58)** | **p-values** |
| **Age (yrs)** | **7.3±3.7** | **6.3±2.8** | **0.110** |
| **Log Body Mass Index** | **2.8±0.2** | **2.8±0.2** | **0.836** |
| **Gender (% Female)** | **36.7** | **34.5** | **0.804** |
| **DPTRS** | **7.1±0.3** | **7.2±0.4** | **0.269** |
| **Index60** | **0.8±0.5** | **1.0±0.5** | **0.212** |
| **AUC Glucose (mg/dl)/120 min** | **124.2±11.5** | **122.0±13.3** | **0.327** |
| **AUC C-peptide (ng/ml)/120 min** | **3.8±1.5** | **3.5±1.2** | **0.130** |

 **Diabetes Prevention Trial Type-1 Risk Score (DPTRS)**

The DPTRS was derived from the Diabetes Prevention Trial-Type 1 study and validated in the Trialnet Pathway to Prevention study. The calculation of the score (shown below) is based upon coefficients derived from proportional hazards regression**.**

0.813 × [Glucose Sum (mg/dl)/100] - 0.848 × [C-peptide Sum (ng/ml)/10] - 0.056 × [Age (years)]

+1.569 × [log-BMI (kg/m2)] +0.476 × [log-Fasting C-peptide (ng/ml)]

(Glucose and C-peptide Sums are from 30 + 60 + 90 +120 minute totals)

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