**Closed Loop Open SourcE In Type 1 diabetes trial (CLOSE IT). Efficacy of a fully closed loop system for the management of Type 1 diabetes**

**Aim**

Current automated insulin delivery (AID) systems require manual insulin bolus delivery pre-meal (hybrid closed-loop; HCL). Efficacy data are needed on AID without meal announcement (fully closed-loop; FCL). We aimed to determine efficacy of a FCL system using Android Artificial Pancreas System, oref, in adults with Type 1 diabetes (T1D).

**Methods**

Randomised, open-label, parallel, non-inferiority trial, non-pregnant T1D (>1 year) adults (18-70 yo) were recruited. Post-training participants were established on an open-source AID system, with meal announcement for a 12-week run-in, then assigned (1:1) to FCL (no meal announcement) or HCL (continued meal announcement) for 12-weeks. The primary outcome was the percentage of time in target glucose range (TIR) 3.9 -10.0 mmol/l) in the final 2-weeks of the trial, adjusted for the same metric in the final 2-weeks of the run-in phase, with a non-inferiority margin of 7 percentage points difference.

**Results**

Seventy-three participants were randomised (36 to FCL and 37 to HCL) with similar baseline demographics. Mean (±SD) TIR at end of run-in and trial-end phases were 69±11% and 66±8% in the FCL, and 70±9% and 69±13% in the HCL group (95% confidence interval, -6.2 to 1.7; p=0.009 for non-inferiority). HbA1c was 6.9±0.7% and 6.9±0.6% and 6.8±0.6% and 6.8±0.6% for HCL (NS). There was no significant difference in % TBR. Figure shows CGM plots by treatment arm.

**Conclusions**

In adults with T1D, AID system use as FCL was non-inferior to the system used as HCL re TIR and safety.

