

Automated Insulin Delivery for Inpatients With Dysglycemia (AIDING) Randomized Controlled Trial

NCT06418880

November 7, 2025

# **Automated Insulin Delivery for Inpatients with Dysglycemia (AIDING) Randomized Controlled Trial**

## **Statistical Analysis Plan**

**Version 1.2**

**November 7, 2025**

**Based on Protocol Version 1.8**

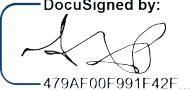
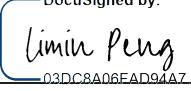
## Version History

Version	Principal Investigator	Statistician	Effective Date	Protocol Version
1.2	Francisco Pasquel	Limin Peng	11/07/2025	1.8

Changes and Clarifications:

Clarifications regarding intent-to-treat (ITT) and per-protocol (PP) analyses (sensitivity analysis). The primary analysis will follow the intent-to-treat (ITT) principle, including all randomized participants. The per-protocol (PP) sensitivity analysis will be limited to participants meeting data sufficiency criteria ( $\geq 70\%$  of data per patient day and  $\geq 24-48$  hours of sensor wear; Spanakis et al., 2023). Clarification of reference related to power calculations and standard deviations based on prior studies and the pilot trial. Expanded baseline descriptive variables to include education, income, and corticosteroid use, as well as planned inclusion of corticosteroid exposure in subgroup exploratory analysis.

## Approvals

Name	Role	Signature
Francisco Pasquel, MD, MPH	PI	 DocuSigned by: 11/12/2025   10:31 AM EST 479AF00F991F42F...
Limin Peng, PhD	PhD	 DocuSigned by: 11/12/2025   11:21 AM EST 03DC8A06EAD9AA7

## I. Study Overview

In this study, there will be two arms (AID + remote monitoring vs. standard-of-care insulin therapy with CGM) and the primary outcome being measured is % time within glucose ranges of 70-180 mg/dL using a continuous glucose monitoring (CGM) system. The main inclusion criteria are:

- Type 1 Diabetes or Type 2 Diabetes
- $\geq 18$  years old

**Table 1. Study Summary**

<b>Project Title</b>	Automated Insulin Delivery for Inpatients with Dysglycemia (AIDING) Randomized Controlled Trial
<b>Précis</b>	This randomized controlled trial will test the efficacy and safety of automated insulin delivery (AID) in hospitalized patients with diabetes (type 1 or type 2) requiring insulin therapy who are admitted to general medical/surgical floors. Participants will be randomized to AID + remote CGM (intervention) or multiple daily insulin injections (MDI) + CGM (control group). Participants will be followed for a total of 10 days or until hospital discharge (if less than 10 days).
<b>Study Design</b>	Open label, multicenter, randomized (1:1), parallel-group, clinical trial.
<b>Objectives</b>	<p><u>Primary objective:</u> To test the efficacy and safety of AID versus standard of care therapy in the inpatient setting.</p> <p><u>Secondary objectives:</u> To determine differences in CGM derived metrics between AID and standard of care therapy in the hospital and explore differences in treatment effect according to individual characteristics.</p>
<b>Research Intervention</b>	The Omnipod 5 system, consists of a disposable insulin infusion pump (or “pod”), a built-in model predictive control (MPC) insulin dosing algorithm, and a remote smartphone interface (Controller), that interact with a Dexcom G7 continuous glucose monitor (CGM) to automatically control insulin delivery based upon real-time glucose values. The Controller component also enables remote interaction with the system, including glucose monitoring as well as insulin dosing management and adjustments. The control group will wear a Dexcom G7 CGM.
<b>Treatment Groups</b>	Participants will be randomized to AID + CGM or to MDI + CGM for up to 10 days or until hospital discharge.
<b>Population</b>	<p><b>Key Inclusion Criteria:</b></p> <p>Any person <math>\geq 18</math> years of age with diabetes mellitus (except cystic fibrosis- and pregnancy-related) admitted to general (non-ICU)</p>

	<p>medical-surgical hospital services who requires inpatient insulin therapy (i.e.,T1D or T2D with <math>\geq 2</math> glucose values <math>\geq 180\text{mg/dl}</math>)</p> <p><b>Key Exclusion Criteria:</b></p> <ul style="list-style-type: none"> <li>• Patients admitted to ICU</li> <li>• Patients anticipated to require less than 48 hours admission</li> <li>• Current evidence of hyperglycemic crises (diabetes-related ketoacidosis or hyperosmolar hyperglycemic state)</li> <li>• Severe anemia with hemoglobin <math>&lt;7\text{ g/dL}</math></li> <li>• Evidence of hemodynamic instability</li> <li>• Hypoxia (<math>\text{SpO}_2 &lt;92\%</math> on supplemental oxygen)</li> <li>• Pre-admission or inpatient total-daily insulin dose <math>&gt;150\text{ units daily}</math></li> <li>• Patients with T2D on correctional insulin therapy alone.</li> <li>• Patients without diabetes with stress hyperglycemia (not related to steroids or medical nutrition therapy) and with <math>\text{HbA1c} &lt;6.5\%</math></li> <li>• Patients on AID as outpatient</li> <li>• Patients with a condition impeding their ability to consent or answer questionnaires</li> <li>• Patients who are pregnant at time of enrollment</li> <li>• Patients who are unable or unwilling to use rapid-acting insulin analogs (Humalog, Admelog, or Novolog during the study)</li> <li>• Active use of a substance known to interfere with CGM accuracy, including hydroxyurea, high dose acetaminophen (<math>&gt;4\text{ grams/day}</math>), or high dose ascorbic acid (<math>&gt;500\text{ mg/day}</math>)</li> </ul>
<b>Sample Size</b>	120 participants
<b>Planned Enrollment</b>	Up to 135 participants
<b>Number of Sites</b>	3
<b>Endpoints</b>	<p><b>Primary Endpoints:</b></p> <p>Efficacy: time spent in glucose target range (TIR, 70-180 mg/dl)</p> <p>Safety: time spent below range (TBR, <math>&lt;54\text{ mg/dl}</math>)</p> <p><b>Key Secondary Endpoints:</b></p> <p>Time spent above range (TAR <math>&gt;250\text{ mg/dl}</math>)</p> <p>Mean hospital glucose</p> <p>TBR <math>&lt;70\text{ mg/dl}</math></p> <p><b>Other Secondary and Exploratory Endpoints:</b></p> <p>Time spent above 180 mg/dl (TAR <math>&gt;180\text{ mg/dl}</math>)</p> <p>Time spent between 70-99 mg/dl</p>

	<p>Glycemic events above 300 mg/dl and below 54 mg/dl</p> <p>Glycemic variability (coefficient of variation)</p> <p>Differences in treatment effect according to individual characteristics (age, sex, BMI, HbA1c, renal function, and type of diabetes).</p> <p>Proportion of participants that spend &gt;70% of time in target range (70-180 mg/dl) without hypoglycemia</p> <p>Significant hyperglycemic events (glucose &gt;400mg/dl)</p>
	<p><b>Key Safety Outcomes:</b></p> <ul style="list-style-type: none"> <li>• <u>Reportable hypoglycemia</u>: glucose level &lt;40mg/dl (POC or central lab) defined as an event that required assistance due to altered consciousness to actively administer <i>parenteral</i> dextrose or glucagon. This means that the participant was impaired cognitively to the point that the participant was unable to drink or eat oral carbs (e.g. juice, crackers), was incoherent, disoriented, and/or combative, or experienced seizure or coma.</li> <li>• <u>Diabetes-related ketoacidosis (DKA)</u> or <u>hyperosmolar hyperglycemic syndrome (HHS)</u></li> </ul>
<b>Participant Duration</b>	Up to 10 days during the inpatient stay; optional extension of wear at investigator discretion (up to 10 additional days)
<b>Funding Source</b>	NIDDK

## II. Sample Size Calculation and Power Analysis

**Table 2** below represents the total sample size requirements for different combinations of SD and treatment differences. The assumptions are normality of the treatment effect, 1:1 allocation ratio, two-tailed test with the null hypothesis no difference exists, 90% power, 17.3% standard deviation estimated (SD) by the investigators from the literature, and type I error of 5%. A SD of 16% was observed in our recently completed feasibility trial.

**Table 2. Sample size estimates**

<b>Treatment Effect</b>			
<b>5%</b>	<b>10%</b>	<b>15%</b>	<b>20%</b>
N=504	N=126	N=56	N=32

It should be noted, sample sizes are typically increased by 10-15% to account for potential dropout.

An N=100 gives a power of 99% to detect a difference of 15% between groups at a standard deviation of 16% (AIDING pilot) or 17.3% (prior trials) and  $\alpha=0.05$ . An N=56 gives a power of 90% to detect a difference of 15%. To include at least 20 participants in subgroups of interest (T1D, renal disease, and steroid exposure) for the exploratory analysis and at least 100 participants with  $\geq 48$  hours of device use for the efficacy and safety analysis, we will enroll a total of 120 participants with sufficient CGM data.

**CGM Data Sufficiency Definition:** A minimum of 70% of data per patient day and a minimum of 24 hours in sensor duration will serve as the thresholds for inclusion in the per-protocol analysis (Spanakis et al 2023).

**Table 3** shows the minimum detectable differences for a range of sample sizes.

**Table 3. Minimum detectable differences**

Total N	Min. Detectable Difference
<b>14</b>	32.7%
<b>20</b>	26.5%
<b>30</b>	21.2%
<b>44</b>	17.3%
<b>60</b>	14.7%
<b>128</b>	9.99%

T1D, due to its low incidence compared to T2D, will be a difficult subgroup to analyze with any statistical rigor (e.g., if 14 participants with T1D are enrolled, a mean difference of 32.7% would have to be observed to achieve 90% power). We anticipate a roughly 20% difference in time in range (TIR), among participants with T1D. We will have about 80% power to detect a 20% or larger difference in TIR with 10 participants with T1D per group, which is sufficient for an exploratory analysis. We aim to include at least 20 participants in subgroups of interest (T1D, steroid exposure, kidney disease).

Looking at N=56, 72, and 100, standard deviation=16% - 17.3%, and mean differences in % TIR ranging from 10-20%, we calculated the power and found in all scenarios we would achieve greater than 90% power to find a difference larger than 15% for the primary endpoint, **Table 4**.

**Table 4. Power analysis.**

Effect Size	Power (SD 17.3%) Prior studies			
	N=20	N=56	N=72	N=100
<b>10%</b>	0.253	0.580	0.689	0.816
<b>12%</b>	0.342	0.738	0.837	0.930
<b>14%</b>	0.440	0.857	0.930	0.980
<b>15%</b>	0.492	0.901	0.957	0.990

<b>16%</b>	0.543	0.933	0.975	0.996
<b>20%</b>	0.734	0.991	0.998	0.999
<b>Power (SD 16%) – AIDING Pilot</b>				
<b>Effect Size</b>	<b>N=20</b>	<b>N=56</b>	<b>N=72</b>	<b>N=100</b>
10%	0.287	0.648	0.755	0.878
12%	0.389	0.801	0.889	0.963
14%	0.499	0.906	0.960	0.992
15%	0.554	0.939	0.978	0.997
16%	0.609	0.963	0.989	0.999
20%	0.798	0.997	0.999	0.999

## Background Information for % TIR estimates and standard deviation

### Standard deviation estimates

SD inputs for the sample size calculations were taken from Hovorka *et al.* (2018) and other literature searches regarding closed-loop system use in Hovorka *et al.*, SDs ranged from 16-25% for different subgroups, with the overall SDs being 16.8% and 16.9% for the closed-loop and daily insulin injections groups, respectively.

Most standard deviations range from 16-23% with mean % TIR for closed-loop systems around 65%. A SD of 16% was observed in our recently completed feasibility trial. **Table 5**.

**Table 5 – Reference list of mean % TIR and associated standard deviations for similar studies.**

Study	Method	Mean	SD	Population	Setting	Notes
Hovorka (Lancet, 2018)	Closed-loop	65	8	T1D	>6 yrs old	
Hovorka (Lancet, 2018)	Sensor-augmented	54	9	T1D	>6 yrs old	
Hovorka (NEJM, 2018)	Closed-loop	65.8	16.8	T2D	Adult in-patient	
Hovorka (NEJM, 2018)	MDI	41.5	16.9	T2D	Adult in-patient	
Philis-Tsimikas (Diabetes Care, 2020)	GCM	25.31*	23	T2D	Adult in-patient	*Medians reported and SD estimated roughly from IQR
Philis-Tsimikas (Diabetes Care, 2020)	MDI	19.98*	27	T2D	Adult in-patient	*Medians reported and SD estimated roughly from IQR

Spanakis (Diabetes Care, 2020)	GCM	59.12	22**	T2D	Adult in-patient	**Estimated from 95% CI
Spanakis (Diabetes Care, 2020)	MDI	54.69	22**	T2D	Adult in-patient	**Estimated from 95% CI
Davis (DTT 2023)	AID	68	16	T1D /T2D	Adult in-patient	

## References (Table 5)

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### III. Statistical and Analytical Plans

The sample size and analytical plans are summarized below.

#### Statistical Hypotheses

This trial has a primary outcome of percent time in range (% TIR), defined as CGM-measured glucose between the range of 70-180 mg/dL. This will be tested using a two-sided test of superiority. The two groups being compared are those using the Dexcom G7 in conjunction with the Omnipod 5 (automated insulin delivery) and those receiving the standard of care (multiple daily injections of insulin with CGM for detection of hypoglycemia). Participants will be followed for a minimum of 48 hours and a maximum of 10 days. The study will be conducted in an in-patient hospital setting (non-ICU) across three sites and will include any participant with diagnosed diabetes (e.g., T1D, T2D) requiring insulin treatment.

Hypotheses:

- a. *Null Hypothesis:* There is no difference in % TIR between the Standard of Care (control) and AID (experimental) groups.
- b. *Alternative Hypothesis:* there is a difference in % TIR between the Control and Experimental groups.

#### Sample Size

The assumptions for the sample size calculations were as follows: (1) normality of the response variable, i.e., % TIR; (2) two-sided test of superiority; (3) a difference in response of 15%; (4) standard deviation of 16%; (5) 99% power; (6) two-sided type I error rate of 5%; and (7) 1:1 allocation ratio between AID and multiple daily injections (MDI).

A sample size of N=100 gives a power of 99% to detect a difference of 15% at a standard deviation of 16% and  $\alpha=0.05$  based on our pilot trial. To account for patients not completing 24hrs on device and to allow for a minimum sample of 20 participants with T1D we will enroll up to 135 participants. We anticipate a larger effect, a roughly 20% difference in time in range (TIR) among participants with T1D and we will have 80% power to detect a 20% or larger difference in TIR with 10 participants with T1D per group, which is sufficient for an exploratory analysis.

#### Outcome Measures

Outcomes measured using a CGM system

**Primary Efficacy Endpoint:**

- % TIR (superiority).

**Primary Safety Endpoint:**

- % TBR <54 mg/dl (non-inferiority followed by superiority)

**Secondary Efficacy Endpoints as Part of a Statistical Hierarchy:**

1. % TIR (primary)
2. Percent time >250 mg/dL (superiority)
3. Mean glucose (superiority)
4. Percent time <70 mg/dL (non-inferiority)
5. Percent time <70 mg/dL (superiority)

**Other Secondary Outcomes – Insulin Analyses**

- Basal insulin
- Bolus amounts
- Total daily insulin dose

**Other Secondary Outcomes – CGM Metrics**

- Glycemic events below 54 mg/dL
- Glycemic events above 300 mg/dL and >400mg/dL
- Glycemic variability (as measured by the coefficient of variation)
- Percent time 70-99 mg/dl

**Description of Statistical Methods**

**General Approach**

The intent-to-treat (ITT) approach will be used with each participant analyzed in the group to which they were randomized regardless of treatment received. A sensitivity (per-protocol) analysis

will also be conducted for participants with >24 and 48 hours of data. This analysis will assess the robustness of the primary findings to protocol adherence and sufficient exposure to AID.

All p-values, unless otherwise noted, will be two-sided. Percent time below 70 mg/dL and time below 54 mg/dL will initially be tested as non-inferior; if the alternative hypothesis is not rejected, these metrics will then be tested for superiority. Time below 54 mg/dL will be tested separately (primary safety endpoint).

It is expected % TIR will be normally distributed and can be assessed with a standard linear regression approach. If residuals are skewed, a nonparametric or robust regression approach will be used. Other outcomes not normally distributed will also be assessed using a nonparametric or robust regression approach. The outcomes most likely to be skewed from past experience are the % time below 70 mg/dL and 54 mg/dL.

## **Analysis Cohorts**

### **Safety Analyses**

All safety outcomes will be reported for all participants throughout the study.

Any baseline factors found to be imbalanced between treatment groups will be added as covariates to the analysis.

## **Analysis of Percent Time in Range (% TIR)**

The primary outcome is % TIR for the control and AID. To compare the two groups, a linear regression model will be used using the covariates age, insulin treatment, baseline HbA1c, diabetes type, and site (random effect). The point estimate for difference in treatment effect, 95% confidence interval, and p-value for the mean % TIR difference will be reported. Summary statistics for each group will also be reported. Residuals will be checked for skewness and, if found to be highly skewed, a non-parametric or robust estimation method will be used.

## **Hierarchical Outcomes and the Hypothesis Testing Procedure**

### **Hierarchical Testing**

The hierarchical outcomes to be tested and their order is as follows:

1. % TIR (superiority)
2. Percent time >250 mg/dL (superiority)
3. Mean glucose (superiority)
4. Percent time <70 mg/dL (non-inferiority – 2.5% limit)
5. Percent time <70 mg/dL (superiority)

To preserve the over type I error rate, a hierarchical approach will be used. Hypothesis testing starts with the first outcome (TIR) and continues down the list unless/until a non-statistically significant result ( $p>0.05$ ) occurs. If one of the hypothesis tests results in  $p>0.05$ , then none of the remaining outcomes (if any) lower on the list will be formally tested. Summary statistics with 95% confidence intervals will be reported for all outcomes on the list regardless of statistical significance.

The primary safety outcome (% time <54 mg/dl) will be analyzed separately, with initial testing for non-inferiority followed by superiority, if appropriate. With a non-inferiority margin of 0.5% for % time <54 mg/dL [Null hypothesis (H0):  $\mu\delta \geq 0.5\%$ ] a sample size of 14 provides 90% power to confirm the lower limit of the 95% CI is above -0.5% (Alternate hypothesis (Ha):  $\mu\delta < 0.5\%$ ).

A robust regression method may be used for % time >300 mg/dL and % time <54 mg/dL as these metrics are most likely to be skewed away from normality. For glycemic variability, a linear regression model can be used; if highly skewed, a robust regression method can be used instead. Covariates used will be similar as those used in the primary outcome analysis.

## **Insulin Analyses**

Average daily insulin units will be compared between the treatment groups in the same fashion as described for the primary outcome, as well basal insulin and bolus amounts.

## **Safety Analyses**

All participants will be included in the safety analyses.

The circumstances of all reportable adverse events (AE) from the following list will be summarized and tabulated by treatment group:

- Severe hypoglycemic events
- Hyperglycemic crisis (DKA/HHS) events
- CGM-measured hypoglycemia events <54 mg/dL (15 or more minutes)
- Other serious adverse events (SAE)
- Unanticipated adverse device effects (UADE)
- Adverse device effects (ADE)
- Other adverse events

Statistical analyses to compare rates of severe hypoglycemia events between treatment arms will only be performed if there are at least 5 total events after randomization in both groups. If so, the numbers will be compared between the two treatment periods using a robust Poisson regression. The amount of follow up will be included as an offset covariate to compare the rates.

## **Device Issues**

Device issues and complaints will be tabulated and reported for each group.

### **Protocol Adherence**

The following tabulations will be done for each treatment group:

- Number of deviations per participant and the percentage of participants with each deviation.
- Protocol deviations by severity.
- Flow chart accounting for participants.
- Descriptions for participants who withdrew.
- Number of days in the trial for each participant and reason for ending.

### **Baseline Descriptive Statistics**

Baseline descriptive statistics will be tabulated for each treatment group with appropriate summary statistics used for the distribution. The characteristics used will include:

- Reason for hospitalization
- Age
- Sex
- Race/ethnicity
- Insurance status
- Education
- Income
- Diabetes duration
- Diabetes type
- BMI
- Glucose at randomization
- Diabetes treatment
- HbA1c
- Relevant labs (HbA1c, creatinine, eGFR)
- Comorbidities
- Corticosteroid use during the trial

### **Planned Interim Analysis**

No interim analyses are planned.

### **Subgroup Description**

Outcomes will be assessed for subgroup characteristics by treatment group if they are found to be statistically significant. The baseline factors will include:

- Baseline HbA1c
- Baseline glucose
- Age
- Sex
- Race/ethnicity
- Insurance status
- Diabetes type
- Kidney disease
- Corticosteroid use
- Pre-study insulin use

### **Multiple Comparison/Multiplicity**

Type I error rate inflation will be controlled in the primary and secondary outcomes using a hierarchical system.

For the exploratory subgroup analysis of diabetes subtypes, the Benjamini-Hochberg method of FDR adjustment will be used to account for potential multiplicity.

### **Exploratory Analyses**

As a subgroup analysis, differences in treatment effect will be examined. Including comparisons of treatment across BMI ranges, sex, HbA1c, steroid use, and renal function. It is expected most cases (~80%) will be T2D cases. To explore differences in treatment effect among participants with T1D we will enroll a minimum of 20 participants with T1D.

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Certified Delivered

Security Checked

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Signing Complete

Security Checked

11/12/2025 11:21:18 AM

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