

The Effect of Basal Insulin During Exercise on the Development of Hypoglycemia in Children with Type 1 Diabetes

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**DirecNet Exercise 2 Study
Enrollment Visit Form**

A. Identifying Information

1. Namecode: _____	2. Patient Initials: _____ (Enter "X" if no middle initial)
3. Date of birth: _____ / _____ / _____ mm/dd/yy	(Age must be ≥8.0 to <18.0 yrs for eligibility)
4. Informed Consent Form signed by the parent/guardian on _____ / _____ / _____ mm/dd/yy	
5. Child Assent Form signed by the subject on _____ / _____ / _____ mm/dd/yy	
6. Study ID of Enrolling Investigator ____--_____	

Enrollment Visit History Form

1. Enrollment Visit Date: _____ / _____ / _____ mm/dd/yy
2. Study ID of Investigator ____--_____

B. Exclusion Criteria

<p>1. All of the following are study exclusions. Verify by checking each box that none are present.</p> <p><input type="checkbox"/> Current use of glucocorticoids</p> <p><input type="checkbox"/> Current use of beta blocker</p> <p><input type="checkbox"/> Asthma which has been medically treated in the last yea</p> <p><input type="checkbox"/> A recent injury to body or limb, Addison's disease, muscular disorder, use of any medication or other significant medical disorder that in the judgment of the investigator might interfere with the completion of the protocol</p> <p><input type="checkbox"/> Anticipating a significant change in exercise regimen between scheduled visits (i.e. starting or stopping an organized sport)</p>

C. Demographic Information

1. Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female
2. Ethnicity: <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown/not reported
3. Race (select one): <input type="checkbox"/> White <input type="checkbox"/> Black/African-American <input type="checkbox"/> Native Hawaiian/Other Pacific Islander <input type="checkbox"/> Asian
<input type="checkbox"/> American Indian/Alaskan Native <input type="checkbox"/> More than one race <input type="checkbox"/> Unknown/not reported

D. Diabetes History

1. Date of diagnosis of diabetes: _____ / _____ mm/yy (Must be ≥18 months for eligibility)
2. Dx of Type I diabetes: <input type="checkbox"/> Yes <input type="checkbox"/> No (Must be YES for eligibility)
3. Length of insulin pump use: <input type="checkbox"/> 1 mon-<6 mon <input type="checkbox"/> 6 mon -<1 yr <input type="checkbox"/> 1-<2 yrs <input type="checkbox"/> 2-<5 yrs <input type="checkbox"/> ≥5 yrs
4. Insulin to Carbohydrate Ratios (Complete units per grams of carbs or check not used):
4a. Breakfast Insulin to Carb Ratio: 1 unit per _____ grams of carbohydrates <input type="checkbox"/> Not Used
4b. Lunch Insulin to Carb Ratio: 1 unit per _____ grams of carbohydrates <input type="checkbox"/> Not Used
4c. Dinner Insulin to Carb Ratio: 1 unit per _____ grams of carbohydrates <input type="checkbox"/> Not Used
4d. Bedtime Snack Insulin to Carb Ratio: 1 unit per _____ grams of carbohydrates <input type="checkbox"/> Not Used
5. Usual Meal Bolus Doses: Breakfast: _____ Lunch: _____ Dinner: _____ Snack: _____ Bedtime Snack: _____
6. Average Correction (Sensitivity) Factors: 1 unit per _____ mg/dl above _____ mg/dl <input type="checkbox"/> Not Used
7. Number of hypoglycemic seizures/loss of consciousness in last 6 months: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> >3

E. Socioeconomic Information

1. Please circle the highest level of education completed by the primary caregiver(s):														
1a. Mother , Father, Other	<4	4	5	6	7	8	9	10	11	12	AA	BS/BA	MS/MA	Professional Degree (eg MD)
1b. If Other caregiver: Grandmother Grandfather Aunt Uncle Older Sibling														
<i>Please Circle One</i>														
1c. Mother, Father	<4	4	5	6	7	8	9	10	11	12	AA	BS/BA	MS/MA	Professional Degree (eg MD)

Enrollment Visit Physical Examination Form

F. Physical Exam

1. Exam Date ____ / ____ / ____ mm/dd/yy <i>(Must be within 14 days of enrollment visit)</i>	
2. Weight: ____ . ____ kg	3. Height: ____ . ____ cm
<i>(Must be ≥39.5 kg for reinfusion and ≥46.0 for discard centers for eligibility)</i>	
<i>(Body Mass Index (BMI) must be between 5th and 95th percentiles for age and gender. Click here to calculate BMI for eligibility)</i>	

G. HbA1c

1. Date of Test: ____ / ____ / ____ <i>(Must be within 14 days of enrollment visit)</i>	2. HbA1C (from DCA2000): ____ . ____ % <i>(Must be ≤10.0% for eligibility)</i>
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Comments

**DirecNet Exercise 2 Study
Visit Form**

1. Visit Date: ____ / ____ / ____ mm/dd/yy	2. Visit Type: <input type="checkbox"/> Basal Continued <input type="checkbox"/> Basal Stopped
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A. Eligibility Assessment

1. Did the subject have any severe episodes of hypoglycemia (caused the subject to faint or have a seizure) during the last 14 days? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>(If YES, the visit must be deferred.)</i>
2. Has the subject used pseudoephedrine in the past 48 hours? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>(If YES, the visit must be deferred.)</i>
3. Does the subject have an active infection? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>(If YES, the visit must be deferred.)</i>
4. Does the subject have more than small urine ketones present or blood ketones >1.0? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>(If YES, the visit must be deferred.)</i>

B. Hypoglycemia Information

1. How many episodes of symptomatic hypoglycemia did the subject experience in the last 7 days? _____
2a. How many symptomatic episodes were confirmed with an HGM test? _____
2. When was the subject's last symptomatic hypoglycemic episode? <input type="checkbox"/> Last 7 days <input type="checkbox"/> 2-4 wks <input type="checkbox"/> >1 mon <input type="checkbox"/> Never
3. When was the subject's last severe hypoglycemic episode (hypoglycemia resulting in seizure or loss of consciousness)? <input type="checkbox"/> 2-4 wks <input type="checkbox"/> 1 - 6 mon <input type="checkbox"/> 6 - 12 mon <input type="checkbox"/> >1 yr <input type="checkbox"/> Never

C. Physical Activity

Instruct subject to add up all the time he/she spends in physical activity each day.

1. Over the past 7 days, on how many days were you physically active for a total of at least 60 minutes per day? <input type="checkbox"/> 0 days <input type="checkbox"/> 1 day <input type="checkbox"/> 2 days <input type="checkbox"/> 3 days <input type="checkbox"/> 4 days <input type="checkbox"/> 5 days <input type="checkbox"/> 6 days <input type="checkbox"/> 7 days
2. Over a typical or usual week, on how many days are you physically active for a total of at least 60 minutes per day? <input type="checkbox"/> 0 days <input type="checkbox"/> 1 day <input type="checkbox"/> 2 days <input type="checkbox"/> 3 days <input type="checkbox"/> 4 days <input type="checkbox"/> 5 days <input type="checkbox"/> 6 days <input type="checkbox"/> 7 days

D. CGMS Information

1. Monitor Serial Number _____
2. Sensor Lot Number: _____
3. Time of Insertion: ____ : ____ <input type="checkbox"/> AM <input type="checkbox"/> PM
4. Insertion Side: <input type="checkbox"/> Right <input type="checkbox"/> Left
5. Insertion Area (select one): <input type="checkbox"/> Abd-UQ <input type="checkbox"/> Abd-LQ <input type="checkbox"/> Buttocks <input type="checkbox"/> Thigh <input type="checkbox"/> Hip <input type="checkbox"/> Other

E. Freestyle Meter *(Record the serial # of the Freestyle meter that will be used; same test strip lot must be used for the entire admission.)*

1. Freestyle Serial Number _____
2. Test Strip Lot Number: _____
3. Control Test was in normal range: <input type="checkbox"/> Yes <input type="checkbox"/> No

G. Time Synchronization

At the time the CGMS is inserted, be sure that the times on the CGMS, Freestyle, and HR monitor are synchronized with the room clock.

<p>1. Room Clock: ___ : ___ <input type="checkbox"/> AM <input type="checkbox"/> PM</p> <p>The CGMS, Freestyle, and HR Monitor are synchronized with the room clock: <input type="checkbox"/> Yes <input type="checkbox"/> No</p>

COMMENTS

DirecNet Exercise 2 Study Freestyle Blood Glucose Monitoring Form

1. Visit Date: ____ / ____ / ____ mm/dd/yy	2. Visit Type: <input type="checkbox"/> Basal Continued <input type="checkbox"/> Basal Stopped
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A. PRE-EXERCISE BLOOD GLUCOSE MONITORING (From Venous Samples)

Record "E" if error received.

Type	Time	Missed <input checked="" type="checkbox"/>	Freestyle Value
1:00 PM			
2:00 PM			
3:00 PM			

B. EXERCISE BLOOD GLUCOSE MONITORING (From Venous Samples)

Record all protocol-scheduled exercise Freestyle tests; all samples must be done using venous blood. Record "E" if error received.

Type	Time	Missed <input checked="" type="checkbox"/>	Freestyle Value
Baseline			
1 st Rest Period			
2 nd Rest Period			
3 rd Rest Period			
End of Exercise			
15 min Post-exercise			
30 min Post-exercise			
45 min Post-exercise			

C. ADDITIONAL BLOOD GLUCOSE MONITORING (From Fingerstick or Venous Samples)

Record all non-protocol Freestyle tests (i.e. checks following hypoglycemia). Record "E" if error received.

Time	Freestyle Value	Fingerstick or Venous
		<input type="checkbox"/> F <input type="checkbox"/> V
		<input type="checkbox"/> F <input type="checkbox"/> V
		<input type="checkbox"/> F <input type="checkbox"/> V
		<input type="checkbox"/> F <input type="checkbox"/> V
		<input type="checkbox"/> F <input type="checkbox"/> V
		<input type="checkbox"/> F <input type="checkbox"/> V
		<input type="checkbox"/> F <input type="checkbox"/> V
		<input type="checkbox"/> F <input type="checkbox"/> V
		<input type="checkbox"/> F <input type="checkbox"/> V
		<input type="checkbox"/> F <input type="checkbox"/> V

D. Ketone Testing

Record all ketone testing performed during the visit..

Time	Type	Result
	<input type="checkbox"/> Blood <input type="checkbox"/> Urine	
	<input type="checkbox"/> Blood <input type="checkbox"/> Urine	
	<input type="checkbox"/> Blood <input type="checkbox"/> Urine	
	<input type="checkbox"/> Blood <input type="checkbox"/> Urine	
	<input type="checkbox"/> Blood <input type="checkbox"/> Urine	
	<input type="checkbox"/> Blood <input type="checkbox"/> Urine	

**DirecNet Exercise 2 Study
Exercise Session Form**

1. Admission Date: ____ / ____ / ____ mm/dd/yy	2. Visit Type: <input type="checkbox"/> Basal Continued <input type="checkbox"/> Basal Stopped
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A. EXERCISE DATA

Cycle 1

1. Start Time: ____ : ____ PM	2. Target treadmill settings: Speed ____ Incline ____
3. Record any changes to settings below:	
a. Time: ____ : ____ PM Speed ____ Incline ____	b. Time: ____ : ____ PM Speed ____ Incline ____
c. Time: ____ : ____ PM Speed ____ Incline ____	d. Time: ____ : ____ PM Speed ____ Incline ____
4. Record the time the subject's heart rate reaches 140 BPM: ____ : ____ PM	
5. Record the subject's heart rate at the 10-minute point during the cycle:	
a. 5 minutes: ____ BPM	b. 10 minutes: ____ BPM
c. 15 minutes: ____ BPM	
6. Record the subject's RPE (rating of perceived exertion) at the 10-minute point during the cycle: _____	
7. Did the subject complete all 15 minutes of this cycle? <input type="checkbox"/> Yes <input type="checkbox"/> No	
a. If No, how many minutes of the protocol specified 15 minutes were completed? _____ minutes	
b. If No, indicate the reason all 15 minutes were not completed: <input type="checkbox"/> Exhaustion <input type="checkbox"/> BG \leq 65 mg/dl <input type="checkbox"/> Other _____	

Cycle 2

1. Was Cycle 2 initiated? <input type="checkbox"/> Yes <input type="checkbox"/> No	
a. If No, indicate the reason Cycle 2 was not initiated: <input type="checkbox"/> Exhaustion <input type="checkbox"/> BG \leq 65 mg/dl <input type="checkbox"/> Other _____	
2. Start Time: ____ : ____ PM	3. Target treadmill settings: Speed ____ Incline ____
4. Record any changes to settings below:	
a. Time: ____ : ____ PM Speed ____ Incline ____	b. Time: ____ : ____ PM Speed ____ Incline ____
c. Time: ____ : ____ PM Speed ____ Incline ____	d. Time: ____ : ____ PM Speed ____ Incline ____
5. Record the time the subject's heart rate reaches 140 BPM: ____ : ____ PM	
6. Record the subject's heart rate at the following times during the cycle:	
a. 5 minutes: ____ BPM	b. 10 minutes: ____ BPM
c. 15 minutes: ____ BPM	
7. Record the subject's RPE (rating of perceived exertion) at the 10-minute point during the cycle: _____	
8. Did the subject complete all 15 minutes of this cycle? <input type="checkbox"/> Yes <input type="checkbox"/> No	
a. If No, how many minutes of the protocol specified 15 minutes were completed? _____ minutes	
b. If No, indicate the reason all 15 minutes were not completed: <input type="checkbox"/> Exhaustion <input type="checkbox"/> BG \leq 65 mg/dl <input type="checkbox"/> Other _____	

Cycle 3

1. Was Cycle 3 initiated? <input type="checkbox"/> Yes <input type="checkbox"/> No a. If No, indicate the reason Cycle 3 was not initiated: <input type="checkbox"/> Exhaustion <input type="checkbox"/> BG \leq 65 mg/dl <input type="checkbox"/> Other _____		
2. Start Time: ____ : ____ PM	3. Target treadmill settings: Speed ____ Incline ____	
4. Record any changes to settings below:		
a. Time: ____ : ____ PM Speed ____ Incline ____	b. Time: ____ : ____ PM Speed ____ Incline ____	
c. Time: ____ : ____ PM Speed ____ Incline ____	d. Time: ____ : ____ PM Speed ____ Incline ____	
5. Record the time the subject's heart rate reaches 140 BPM: ____ : ____ PM		
6. Record the subject's heart rate at the following times during the cycle:		
a. 5 minutes: ____ BPM	b. 10 minutes: ____ BPM	c. 15 minutes: ____ BPM
7. Record the subject's RPE (rating of perceived exertion) at the 10-minute point during the cycle: _____		
8. Did the subject complete all 15 minutes of this cycle? <input type="checkbox"/> Yes <input type="checkbox"/> No		
a. If No, how many minutes of the protocol specified 15 minutes were completed? ____ minutes		
b. If No, indicate the reason all 15 minutes were not completed: <input type="checkbox"/> Exhaustion <input type="checkbox"/> BG \leq 65 mg/dl <input type="checkbox"/> Other _____		

Cycle 4

1. Was Cycle 4 initiated? <input type="checkbox"/> Yes <input type="checkbox"/> No a. If No, indicate the reason Cycle 4 was not initiated: <input type="checkbox"/> Exhaustion <input type="checkbox"/> BG \leq 65 mg/dl <input type="checkbox"/> Other _____		
2. Start Time: ____ : ____ PM	3. Target treadmill settings: Speed ____ Incline ____	
4. Record any changes to settings below:		
a. Time: ____ : ____ PM Speed ____ Incline ____	b. Time: ____ : ____ PM Speed ____ Incline ____	
c. Time: ____ : ____ PM Speed ____ Incline ____	d. Time: ____ : ____ PM Speed ____ Incline ____	
5. Record the time the subject's heart rate reaches 140 BPM: ____ : ____ PM		
6. Record the subject's heart rate at the following times during the cycle:		
a. 5 minutes: ____ BPM	b. 10 minutes: ____ BPM	c. 15 minutes: ____ BPM
7. Record the subject's RPE (rating of perceived exertion) at the 10-minute point during the cycle: _____		
8. Did the subject complete all 15 minutes of this cycle? <input type="checkbox"/> Yes <input type="checkbox"/> No		
a. If No, how many minutes of the protocol specified 15 minutes were completed? ____ minutes		
b. If No, indicate the reason all 15 minutes were not completed: <input type="checkbox"/> Exhaustion <input type="checkbox"/> BG \leq 65 mg/dl <input type="checkbox"/> Other _____		

B. TERMINATION OF EXERCISE

1. End Time: ____ : ____ PM
2. Heart rate at termination: ____ BPM
3. RPE (rating of perceived exertion) at termination: ____
4. Treadmill settings at termination: Speed ____ Incline ____
5. Reason for Termination:
<input type="checkbox"/> Exercise Completed
<input type="checkbox"/> Exhaustion
<input type="checkbox"/> BG \leq 65 mg/dl
<input type="checkbox"/> Other _____

Comments

**DirecNet Exercise 2 Study
Meal Log**

1. Visit Date: ____ / ____ / ____ mm/dd/yy	2. Visit Type: <input type="checkbox"/> Basal Continued <input type="checkbox"/> Basal Stopped
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A. Lunch

1. Lunch Start time: ____ : ____ <input type="checkbox"/> AM <input type="checkbox"/> PM
2. Content: ____ g Carbohydrates ____ % Consumed ____ g Protein ____ % Consumed ____ g Fats ____ % Consumed
3. Subject's Estimate of Amount of Carbohydrates: ____ g

B. Dinner

1. Dinner Start time: ____ : ____ <input type="checkbox"/> AM <input type="checkbox"/> PM
2. Content: ____ g Carbohydrates ____ % Consumed ____ g Protein ____ % Consumed ____ g Fats ____ % Consumed
3. Subject's Estimate of Amount of Carbohydrates: ____ g

C. Additional Snacks (for treatment of hypoglycemia)

Time: ____ : ____ <input type="checkbox"/> AM <input type="checkbox"/> PM Content: ____ g Carbs	Time: ____ : ____ <input type="checkbox"/> AM <input type="checkbox"/> PM Content: ____ g Carbs
Time: ____ : ____ <input type="checkbox"/> AM <input type="checkbox"/> PM Content: ____ g Carbs	Time: ____ : ____ <input type="checkbox"/> AM <input type="checkbox"/> PM Content: ____ g Carbs
Time: ____ : ____ <input type="checkbox"/> AM <input type="checkbox"/> PM Content: ____ g Carbs	Time: ____ : ____ <input type="checkbox"/> AM <input type="checkbox"/> PM Content: ____ g Carbs
Time: ____ : ____ <input type="checkbox"/> AM <input type="checkbox"/> PM Content: ____ g Carbs	Time: ____ : ____ <input type="checkbox"/> AM <input type="checkbox"/> PM Content: ____ g Carbs
Time: ____ : ____ <input type="checkbox"/> AM <input type="checkbox"/> PM Content: ____ g Carbs	Time: ____ : ____ <input type="checkbox"/> AM <input type="checkbox"/> PM Content: ____ g Carbs

**DirecNet Exercise 2 Study
Insulin Log**

1. Visit Date: ____ / ____ / ____ (mm/dd/yy)	2. Visit Type: <input type="checkbox"/> Basal Continued <input type="checkbox"/> Basal Stopped
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A. IV Insulin

(Record the units of insulin given to get patient into target range for exercise.)

Time	Units of Regular Insulin
____:____ <input type="checkbox"/> AM <input type="checkbox"/> PM	
____:____ <input type="checkbox"/> AM <input type="checkbox"/> PM	
____:____ <input type="checkbox"/> AM <input type="checkbox"/> PM	
____:____ <input type="checkbox"/> AM <input type="checkbox"/> PM	
____:____ <input type="checkbox"/> AM <input type="checkbox"/> PM	
____:____ <input type="checkbox"/> AM <input type="checkbox"/> PM	
____:____ <input type="checkbox"/> AM <input type="checkbox"/> PM	
____:____ <input type="checkbox"/> AM <input type="checkbox"/> PM	
____:____ <input type="checkbox"/> AM <input type="checkbox"/> PM	
____:____ <input type="checkbox"/> AM <input type="checkbox"/> PM	

Comments

**DirecNet Exercise 2 Study
Final Status Form**

This form is completed for every subject enrolled in the study and is used to record the final subject disposition for both visits. This form is only completed once the status of the subject is final, it is not completed if a visit is deferred or rescheduled.

A. DISPOSITION OF SUBJECT

Select one of the following to indicate the disposition of the subject. (If subject was withdrawn from study, detail reasons in COMMENTS)

- Both visits completed
- Withdrawn prior to completing either of the visits
- Withdrawn prior to completing visit with basal continued
- Withdrawn prior to completing visit with basal stopped

B. ADVERSE EVENTS

1. Did any reportable adverse events occur during either visit? Yes No (If YES, an Adverse Event Form must be completed.)

C. INSULIN

1. Was there a substantial difference in insulin use between the two visits? Yes No

1a. If YES, provide details below:

D. MEALS

1. Was there a substantial difference in meals between the two visits? Yes No

1a. If YES, provide details below:

E. COMMENTS
