SOP-NOD-0005 Blood Glucose Monitoring

STANDARD OPERATING PROCEDURE
Pre-clinical Consortium on Combination Therapies for Type I Diabetes

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Applicable to: ITN Project 1	Category:

Title: Blood Glucose Monitoring

INTRODUCTION/PURPOSE

The goal of this study is to determine the efficacy of anti-CD20 monoclonal antibody therapy (alone), oral insulin (alone), or the combination of anti-CD20 plus oral insulin to reverse hyperglycemia in NOD mice with recent onset autoimmune diabetes.

The purpose of this Standard Operating Procedure is to describe the frequency of blood glucose monitoring at various stages of the study.

DEFINITIONS

Diabetes: Blood glucose >= 250 mg/dl (14 mmol/L)

New onset diabetic: Blood glucose readings of >= 250 mg/dl (14 mmol/L) on two consecutive days.

PROCEDURES

Identification of Study Subjects

1. Beginning at 10 weeks of age, the blood glucose of female NOD mice will be monitored three times a week in the morning (Monday, Wednesday, and Friday).

2. The blood glucose of subjects registering an initial blood glucose reading of >= 250 mg/dl (14 mmol/L) will be measured again the day after the first reading.

3. Subjects exhibiting blood glucose measurements of >= 250 mg/dl (14 mmol/L) on two consecutive days will then be evaluated for eligibility for study enrollment according to the methods and criteria described in *SOP-NOD-0001.00: Subject Identification, Inclusion/Exclusion Criteria, and Study Enrollment*.

Monitoring of Study Participants

1. Once a subject is entered into the study, blood glucose levels will be monitored three times a week for the first three weeks following treatment initiation and then two times a week thereafter until a study endpoint, as defined in *SOP-NOD-0003.00: Study Endpoints*, is met.

DOCUMENTATION TO BE MAINTAINED

The following information should be recorded for all study enrollees: Animal ID, sex, date of birth, overall health status, blood glucose measurements, weight.

REFERENCES TO OTHER APPLICABLE SOPS

SOP-NOD-0001.00: Subject Identification, Inclusion/Exclusion Criteria, and Study Enrollment
SOP-NOD-0003.00: Study Endpoints

REFERENCES

None

FORMS/ATTACHMENTS

None

REVISION HISTORY

Effective Date	Revision	Author	Description of Changes
August 5, 2011	01	T Kupfer	Characters were corrected that imported into Datacloud incorrectly.