

Outcome Measures for Outpatient Hypoglycemia Prevention Studies

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Abstract

Systems are being developed that utilize algorithms to predict impending hypoglycemia using commercially available continuous glucose monitoring (CGM) devices and to discontinue insulin delivery if hypoglycemia is predicted. In outpatient studies designed to test such systems, CGM-measured glycemetic indices will not only be important outcome measures of efficacy but, in certain cases, will be the only good outcome. This is especially true in short-term studies designed to reduce hypoglycemia since the event rate for severe hypoglycemic events is too low for it to be a good outcome, and milder hypoglycemia often will be variably detected. Continuous glucose monitoring inaccuracy can be accounted for in the study design by increasing sample size and/or study duration.

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Abbreviations: (CGM) continuous glucose monitoring, (DirecNet) Diabetes Research in Children Network, (HbA1c) hemoglobin A1c, (JDRF) Juvenile Diabetes Research Foundation, (RCT) randomized control trial, (SH) severe hypoglycemic event, (T1DM) type 1 diabetes mellitus

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