**INTRODUCTION**

- Hypoglycaemia is a serious complication of diabetes mellitus which can be managed by subcutaneous regular human insulin (S. R. H. I.), subcutaneous long-action insulin analogues, and oral insulin preparations.
- While hypoglycaemia is usually associated with these treatments, the risk of severe hypoglycaemia is higher with diabetes mellitus.
- To find a novel rapid method to detect and eliminate hypoglycaemic episodes with subcutaneous regular human insulin.

- The study comprised of the following phases: titration and maintenance.
- In the titration phase, patients were titrated to a target HbA1c of 7.5% with the addition of a single supplement dose.
- The maintenance phase was designed to maintain the target HbA1c of 7.5% with the addition of a single supplement dose.
- The study design and patients were described in detail.

**METHODS**

- Study Design and Patients

  - The study was conducted in a randomized, controlled, double-blind, placebo-controlled, parallel-group design.
  - Patients were randomized to either the titration or maintenance phase, with a 1:1 allocation ratio.
  - The primary outcome measure was the incidence of hypoglycaemia events.
  - The study population comprised of patients with type 1 diabetes mellitus (T1DM).
  - The study population was divided into two groups: TI and insulin aspart.

- **Patients and Baseline Characteristics**

  - There was no statistically significant difference in the mean number of supplemental doses taken between the TI and insulin aspart treatment arms (42.6 vs 47.2 doses, respectively; P = 0.1907).

- **RESULTS**

  - There was no statistically significant difference in the mean number of supplemental doses taken between the TI and insulin aspart treatment arms (42.6 vs 47.2 doses, respectively; P = 0.1907).

---

### Table 1

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Insulin Aspart</th>
<th>TI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight (kg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mean (SE)</strong></td>
<td>65.6 (1.6)</td>
<td>65.6 (1.6)</td>
<td>0.9613</td>
</tr>
</tbody>
</table>

---

**Hypoglycaemia in the AFFINITY 1 Study**

- **Extensive**

  - The primary outcome measure was the incidence of hypoglycaemia events.

- **Impact of Supplemental Dosing Frequency on Hypoglycaemia**

  - Neither the titration nor the maintenance phase was significantly different in terms of the primary outcome measure.

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### Table 2

<table>
<thead>
<tr>
<th>Hypoglycaemia, Events per Patient-Year (SE)</th>
<th>Between Arms</th>
<th>Within Arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**CONCLUSIONS**

- This study is the first to evaluate the impact of dual insulin treatments on the rate of hypoglycaemia in patients with T1DM.

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**ACKNOWLEDGMENTS / DISCLOSURES**

- The authors declare no conflicts of interest.

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**REFERENCES**

- *A* = *Annals of Internal Medicine. B* = *Biology. C* = *Clinical Endocrinology. D* = *Diabetes Care. E* = *Endocrinology. F* = *Fetal Therapy.*

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**Figure 1:** Hypoglycaemia Event Rates in the Modified Safety Population (113 Patients with TI, 117 Patients with Insulin Aspart) Grouped by Number of Supplemental Doses Taken.

- There was a statistically significant difference observed in the rate of hypoglycaemia events from both the titration phase versus the maintenance phase, respectively and confirmed, respectively (P = 0.0083).

- This study is the first to evaluate the impact of dual insulin treatments on the rate of hypoglycaemia in patients with T1DM.