Comparative efficacy of Gan & Lee insulin aspart (GL-ASP) and EU-marketed insulin aspart (NN-ASP), when combined with metformin, in patients with type 2 diabetes mellitus: post-hoc analyses from a multicenter, open-label, randomized, controlled clinical trial

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Table 1: Patient inclusion and exclusion criteria

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<th>Inclusion criteria</th>
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| Aged 18-75 years | Treatment at <6 months prior to screening for pre-diabetes or diabetes (
oldest diagnosis required) |
| Diagnosis of type 1 or type 2 diabetes mellitus* | Intensive insulin treatment (3 months prior to screening) |
| Laboratory confirmed HbA1c ≥7.5% ± 1% | Glucocorticoid use <2 months prior to screening |
| Body mass index ≥18 kg/m² | Insulin treatment <6 months prior to screening |
| Treatment for >3 months prior to screening: | A 24-week, open-label, randomized, controlled clinical trial |
| • metformin (2000–4000 mg/day) | Patients with ≥2 comorbidities or patients with previous severe AEs |
| • ≤3 oral antidiabetic drugs (sulfonylureas, non-sulfonylurea insulin secretagogues, and glucosidase inhibitors) | Patients with contraindications to GL-ASP or NN-ASP |

Table 2: Mean HbA1c in subgroups with baseline HbA1c (a) ≥7.5% and (b) ≥9% and (c) ≥11%.

![Figure 2. Mean HbA1c in subgroups with baseline HbA1c (a) ≥7.5% and (b) ≥9% and (c) ≥11%).](image)

Additional methods

- GL-ASP demonstrated similar efficacy to NN-ASP in patients with T2DM also receiving metformin, irrespective of patients' baseline HbA1c level
- Additional results
  - Similar proportions of patients reported adverse events (AEs) (43.7 vs 41.6, P=0.651) and serious AEs (3.9% vs 0.7%, P=0.054) in GL-ASP and NN-ASP groups, respectively

Discussion

- Baseline HbA1c levels were comparable between treatment groups
- Efficacy
- Safety

References

ABSTRACT #0122

**Background:** A 24-week, open-label, randomized, multicenter, active-controlled, non-inferiority phase 3 confirmatory trial (ChCTR2003139200) compared the efficacy and safety of Gan & Lee insulin aspart (GL-ASP) and reference NovoRapid insulin aspart (NN-ASP) in combination with metformin, in patients with type 2 diabetes mellitus (T2DM) with inadequately controlled blood glucose.

**Objectives:**
- Post-hoc analyses investigated the impact of patients’ baseline glycated hemoglobin (HbA1c) levels on the efficacy of GL-ASP and NN-ASP.

**Methods:** Randomized patients (Table 1) with T2DM received subcutaneous mealtime GL-ASP or NN-ASP (3-4 U/kg) as sole insulin therapy, in combination with metformin (Figure 1). Post-hoc subgroup analysis (subgroups: patients’ baseline HbA1c ≥7.5% to <9%, ≥9% to <11%, ≥11%) investigated mean change from baseline in HbA1c (primary efficacy endpoint) and 2-hour postprandial glucose (PPG) levels.

**Results:** Randomized patients (N=590; GL-ASP: n=441; NN-ASP: n=149) had T2DM, with similar mean age (56 years), disease duration (8.4 years), and HbA1c levels (9.5%) across treatment groups. At 24 weeks, mean HbA1c change was similar between GL-ASP and NN-ASP (P=0.3002), with 2.4% and 2.3% reductions observed in the GL-ASP and NN-ASP groups, respectively, in patients with baseline HbA1c ≥7.5%. Similar effects were observed in patients with baseline HbA1c ≥9% and ≥11% (P=0.7564 and P=0.7439, respectively).

**Discussion:**
- Although not pre-specified, and so to be interpreted with caution, this post-hoc subgroup analysis suggested that patients with higher baseline HbA1c levels experienced greater reductions in HbA1c and 2-h PPG over 24 weeks, as would be expected.