

ABSTRACT

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Patient Reported Outcomes in Adults with Type 2 Diabetes Using Mealtime Insulin Monomer Human (rDNA origin) Inhalation Powder (Technosphere® Insulin Inhalation Powder) or Metformin + Secretagogue or Both

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Background and aims: This study investigated whether Mealtime Insulin Monomer Human (rDNA origin) Inhalation Powder alone or in addition to Metformin + Secretagogue was associated with improved patient reported outcomes (PRO) over Metformin + secretagogue alone.

Materials and methods: In this 24-week randomized, multicenter study adults with type 2 diabetes used Mealtime Insulin Monomer Human (rDNA origin) Inhalation Powder (MIMHIP; n = 177), Metformin + Secretagogue (MS; n = 162) or both (I+MS; n = 169). At 12 weeks, subjects not adequately controlled with MIMHIP or MS were transferred to I+MS. Patient-reported outcomes (PRO) included: the SF-36, assessing health-related quality of life (HRQOL), and the Insulin Treatment Questionnaire (assessing diabetes worries and treatment satisfaction). Intent to treat (ITT) analysis used mixed effect models to estimate differences in mean group changes in PRO from Baseline to week 12 (adjusted for baseline scores); *t* tests assessed within-group change from Baseline to 12 weeks in all groups and from 12 to 24 weeks in patients adding MIMHIP to MS.

Results: At Week 12, SF-36 mental health composite scores (MCS) increased ($p = 0.0010$) in MIMHIP but not in MS or I+MS; the difference in change between MIMHIP and MS was not significant in ITT analysis ($p = 0.0612$), but was in the per protocol population ($p = 0.0233$). MIMHIP improved more than MS in Role-Emotional scores ($p = 0.0044$). At Week 12, SF-36 physical health composite scores (PCS) increased in MIMHIP and I+MS and declined in MS; although none of these changes were significant, the difference in change between I+MS and MS was significant ($p = 0.0084$). I+MS showed greater improvement than MS for Bodily Pain ($p = 0.0148$), Physical Functioning ($p = 0.0020$), and Role Physical scores ($p = 0.0172$); MIMHIP showed greater improvement than MS for Role-Physical scores ($p = 0.0124$). There were no changes in Diabetes Worries from Baseline to Week 12, and no differences in change. There was an increase in Treatment Satisfaction in MIMHIP ($p = 0.0003$) and TM ($p < 0.0001$); these improvements were greater than MS (MIMHIP $p = 0.0116$; I+MS $p = 0.0009$). There was no change in MCS, PCS or Diabetes Worries between Weeks 12 and 24 among subjects who added MIMHIP to MS (n = 79), but treatment satisfaction increased ($p = 0.0007$).

Conclusion: HRQOL and treatment satisfaction improved more among those taking Mealtime Insulin Monomer Human (rDNA origin) Inhalation Powder (with or without oral medications) than those taking oral medications only. Those who added Mealtime Insulin Monomer Human (rDNA origin) Inhalation Powder to oral medications during the trial experienced increased treatment satisfaction.