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Summary

A PHASE III INVESTIGATOR-INITIATED CLINICAL TRIAL COMPARING REMIMAZOLAM WITH PLACEBO FOR SADATION IN JAPANESE PATIENTS UNDERGOING UPPER GASTROINTESTINAL ENDOSCOPY

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UEG Week Copenhagen 2023 | Poster

Oesophagus

October 15, 2023

A Phase III randomized controlled trial in 48 Japanese patients found that remimazolam achieved significantly higher successful sedation rates than placebo during upper gastrointestinal endoscopy (91.9% versus 9.1%, p<0.01).

KEY POINTS

- Remimazolam is a novel ultrashort-acting benzodiazepine studied for endoscopic sedation in a setting where few sedatives are covered by Japanese national health insurance.
- The multicenter double-blind trial randomized patients 4:1 to remimazolam (initial dose 3mg with 1mg additional doses as needed) versus placebo, with successful sedation defined by Modified Observer's Assessment of Alertness/Sedation score ≤4, procedure completion, and two or fewer additional doses per six minutes.
- Median total remimazolam dose was 4.0mg, time to arousal was 0.0 minutes in both groups, and time to regaining ability to walk was 5.0 minutes in the remimazolam group versus 0.0 minutes in placebo (p=0.02).
- The authors suggest remimazolam could be a potential sedation option for endoscopic procedures; the study was funded by Mundi Pharma Co., Ltd.

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