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Summary

INITIAL FEASIBILITY AND SAFETY OF A NOVEL ENDOSCOPIC ULTRASOUND-GUIDED LOCAL DELIVERY SYSTEM FOR AAV-BASED PANCREATIC GENE THERAPY

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Pancreas

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A novel endoscopic ultrasound-guided automated delivery system achieved targeted AAV gene therapy infusion into the pancreas of Yucatan pigs with an encouraging preliminary safety profile.

KEY POINTS

- In 17 Yucatan pigs, EUS-guided AAV infusion using a 25-gauge needle and automated delivery system successfully targeted the pancreatic splenic lobe with no procedure-related adverse events or acute pancreatitis.
- AAV-GFP infusion demonstrated dose-dependent biodistribution with robust activity in up to 80% of cells in the targeted splenic lobe at 3 weeks (62±10% SEM, n=4, highest dose 1.5e14 vector genome), while untargeted pancreatic lobes showed minimal GFP expression.
- Mean serum ALT remained normal at all timepoints; mean serum lipase remained normal at most timepoints with one transient elevation at 4 hours that resolved by 72 hours.
- Lipase elevations at 3-4 weeks post-procedure were attributed to durable GFP expression and immunogenicity of the foreign reporter protein, with significant correlation between pancreatic GFP expression and lipase levels.
- The authors propose this approach may provide a platform for one-time durable treatment of metabolic diseases including diabetes and obesity, pending further development.

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