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Summary

FECAL MICROBIOTA TRANSPLANTATION COMBINED WITH ATEZOLIZUMAB PLUS BEVACIZUMAB IN HEPATOCELLULAR CARCINOMA REFRACTORY TO ATEZOLIZUMAB PLUS BEVACIZUMAB: AN OPEN LABEL, SINGLE-ARM, PHASE II PILOT STUDY (FAB-HCC)

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Single FMT combined with atezolizumab/bevacizumab achieved a 33% objective response rate by mRECIST in 12 patients with advanced HCC refractory to atezolizumab/bevacizumab, with no serious treatment-related adverse events.

KEY POINTS

- The combination was safe with no serious treatment-related adverse events; grade 3-4 events included arterial hypertension (n=5) and proteinuria (n=3) from bevacizumab and one diarrhea from FMT.
- Median progression-free survival was 6.9 months (95% CI 3.0-10.8) by mRECIST and 4.3 months (95% CI 0.2-8.5) by RECISTv1.1.
- FMT produced a significant shift of recipient microbiome toward donor microbiome, with healthy-donor FMT showing higher engraftment than anti-PD-1-responder FMT.
- Treatment was associated with changes in fecal and plasma secondary bile acids, decreased circulating PD-1+ CD8+ T cells, and increased CD32b+ CD14high CD16low monocytes.
- Antibody repertoire stability changed over time and was more pronounced in responders than non-responders, as measured by phage-display immunoprecipitation sequencing of IgG epitopes against gut microbiota and environmental antigens.

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