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Summary

14-DAY TAILORED PCR-GUIDED TRIPLE THERAPY VERSUS 14-DAY NON-BISMUTH CONCOMITANT QUADRUPLE THERAPY FOR HELICOBACTER PYLORI ERADICATION: A MULTICENTER, OPEN-LABEL RANDOMIZED CONTROLLED TRIAL, THE HEPYSE TRIAL

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Stomach & H. Pylori

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A French multicentre randomised controlled trial demonstrated non-inferiority of 14-day PCR-guided tailored triple therapy compared to 14-day non-Bismuth concomitant quadruple therapy for first-line H. pylori eradication in a high clarithromycin resistance setting.

KEY POINTS

- In the intention-to-treat population of 241 randomised patients, eradication rates were 99.2% for tailored PCR-guided therapy (esomeprazole, amoxicillin, and clarithromycin or levofloxacin based on resistance) versus 95.9% for standard concomitant quadruple therapy (esomeprazole, amoxicillin, clarithromycin, and metronidazole), with a difference of +3.30% and lower CI bound of -0.68%.
- Per-protocol analysis showed eradication rates of 98.8% versus 96.5%, with difference of +2.35% and lower CI bound of -3.33%, both meeting the prespecified non-inferiority margin of -5%.
- The tailored PCR-guided approach was associated with significantly fewer adverse events (41.2% versus 61.4%, p=0.003), particularly gastrointestinal adverse events (36.0% versus 57.9%, p=0.001).
- This study may inform clinicians treating H. pylori infection in regions with high clarithromycin resistance who have access to rapid susceptibility testing.

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