

New Modified Helicobacter Test *INFAI*[®]

The accuracy of new breath test with a modified test meal (*Refex*[®]) for *Helicobacter pylori* in patients taking PPI



Abstract: 50-60 % of patients complaining dyspeptic symptoms are using PPIs. It is well recognized that these medications decrease the sensitivity of ¹³C-urea breath test (¹³C-UBT) and stool antigen test to diagnose *Helicobacter pylori*. Therefore, ¹³C-UBT should be used 14 days after stopping PPI.

INFAI performed a multicenter clinical trial. The aim of this study was to determine the efficacy of a specially formulated test meal (*Refex*[®]) in improving the sensitivity and accuracy of the breath test in patients taking PPI.

Patients and Method: 57 consecutive dyspeptic patients infected with H.p. and 45 H.p. negative patients have been studied. Patients were given Nexium[®] (AstraZeneca, AB, Sweden), 40 mg once daily, 30 min before breakfast, every day for 30 days. They were instructed not to take antibiotics, bismuth compounds, H2 receptor antagonists or other acid-suppressive agents during the study period. Patients returned one day after the treatment of 30 days and the ¹³C-UBT with the new test meal was performed. The taking of PPI can then be continued immediately.

Results: Sensitivity, specificity and accuracy of UBT after PPI treatment by using cut-off point of 2.5 % were calculated. The test has a sensitivity of 92.4 % with a specificity of 97.7 % and an accuracy of 95.1 %.

Conclusion: A new test meal (*Refex*[®], containing a mixture of organic acids), increased sensitivity and accuracy of ¹³C-UBT in patients taking PPI. This is the first ¹³C-UBT that can be used in patients regardless of PPI intake with high sensitivity, specificity and accuracy after only one-day stop.

Clinical trial: Malfertheiner P., Tepeš B., Labenz J., Aygen S., The Sensitivity and Specificity of the Modified Helicobacter Test INFAI Using New Test Meal with ¹³C-Urea Breath Test in Helicobacter Pylori Positive and Negative Patients with Dyspepsia Taking Proton Pump Inhibitors, study no.: HPTM11/J/08, Eudra-CT no.: 2008-008010-39.

Canbay A., Tepeš B., Aygen S., The Sensitivity and Specificity of the Modified Helicobacter Test INFAI Using New Test Meal with ¹³C-Urea Breath Test in Helicobacter pylori Positive and Negative Patients with Dyspepsia and GERD Taking Proton Pump Inhibitors, study no.: HPT30/J/17, Eudra-CT no.: 2017-001369-25.

Reference: Tepeš B., Malfertheiner P., Labenz J., Aygen S., Modified *Helicobacter* test using a new test meal and a ¹³C-urea breath test in Helicobacter pylori positive and negative dyspepsia patients on proton pump inhibitors, *World J Gastroenterol* 2017, 23(32): 5954-5961.

Aygen S., Cologne (DE), European Patent EP 1 685 851 B1 „A method for the diagnosis of *Helicobacter pylori* infection and diagnostic kit for performing the method. “