

# Test-and-treat *Helicobacter pylori* for gastric cancer prevention

**First published:** 17/05/2024

**Last updated:** 30/01/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000144

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### Study ID

1000000144

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### DARWIN EU® study

No

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### Study countries

 Croatia

 Ireland

 Latvia

 Poland

 Romania

 Slovenia

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## **Study description**

The aim of this multi-centric prospective study is to apply pilot test of a screening program for *Helicobacter pylori* (*H. pylori*) infection with the proposed test-and-treat strategy in patients between 30-34 years of age at 7 study sites in the European Union (EU). Although there are some differences in the study protocol between individual study sites, a common set of protocol characteristics is followed. Candidate patients will be sampled and invited to participate in the study and to sign the informed consent form. Enrolled participants at 5 screening sites will take a primary serology test, and those with a positive result will take an additional urea breath test (UBT) to confirm an active infection with *H. pylori*. In 2 remaining study sites only UBT will be used for confirmation. Participants with a positive UBT result will undergo primary treatment consisting of 2 antibiotics, a proton pump inhibitor and, in 6 out of 7 study centers, colloidal bismuth. The success of eradication will be afterwards tested by a control UBT. Participants with persisting infection will undergo secondary treatment consisting of 2 antibiotics, a proton pump inhibitor and, in 6 out of 7 study centers, colloidal bismuth, and will be re-tested for eradication by second control UBT. All study sites will collect data on the rate of *H. pylori* eradication, medication adherence and occurrence of adverse events, where NIJZ will enable information technology and data base support. We estimate that the project's prospective cohort will consist of up to 6,800 study participants. All study sites obtained the approval of their local ethics committee. The results of this study will provide evidence-based foundation for the preparation of screening recommendations to implement this strategy within EU as a screening program according to special conditions (EU Recommendation) to reduce the burden of gastric cancer and other health problems associated with *H. pylori* infection.

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## **Study status**

Ongoing

## **Research institutions and networks**

## Institutions

### National Institute of Public Health (NIJZ)

 Slovenia

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**Institution**

Other

- Beacon Hospital
- Clinical Hospital Center Rijeka
- "Iuliu Hatieganu" University of Medicine and Pharmacy Cluj-Napoca
- University Hospital Centre Zagreb
- University of Latvia Institute of Clinical and Preventive Medicine
- Wroclaw Medical University.

## Contact details

### **Study institution contact**

Mitja Oblak mitja.oblak@nijz.si

### Study contact

[mitja.oblak@nijz.si](mailto:mitja.oblak@nijz.si)

### Primary lead investigator

Bojan Tepeš

### Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 14/02/2023

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### Study start date

Planned: 01/02/2024

Actual: 04/03/2024

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### Date of final study report

Planned: 31/03/2026

## Sources of funding

- EU institutional research programme
- Other

## More details on funding

1. HaDEA: Eu4Health programme
2. Ministry of Health

## Regulatory

**Was the study required by a regulatory body?**

No

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**Is the study required by a Risk Management Plan (RMP)?**

Not applicable

Methodological aspects

Study type

Study type list

**Study topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Data collection methods:**

Primary data collection

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**Main study objective:**

The main objective of this study is to test the implementation of a screening program for Helicobacter pylori infection and treatment with the proposed "test-and-treat" strategy in six EU member states.

Study Design

## **Non-interventional study design**

Cohort

## **Study drug and medical condition**

### **Medicinal product name, other**

amoxicillin (any available brand),  
clarithromycin (any available brand),  
levofloxacin (any available brand),  
metronidazole (any available brand),  
tetracycline (any available brand),  
esomeprazole (any available brand), and  
colloidal bismuth (any available brand).

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### **Study drug International non-proprietary name (INN) or common name**

AMOXICILLIN

BISMUTH

LEVOFLOXACIN HEMIHYDRATE

METRONIDAZOLE

TETRACYCLINE

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### **Anatomical Therapeutic Chemical (ATC) code**

(A01AB13) tetracycline

tetracycline

(A01AB17) metronidazole

metronidazole

(A02BC05) esomeprazole

esomeprazole

(A02BX05) bismuth subcitrate

bismuth subcitrate

(J01CA04) amoxicillin

amoxicillin

(J01FA09) clarithromycin

clarithromycin

(J01MA12) levofloxacin

levofloxacin

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### **Medical condition to be studied**

Helicobacter infection

## Population studied

### **Age groups**

- Adults (18 to < 46 years)
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### **Estimated number of subjects**

6800

## Study design details

### **Outcomes**

1. Participation rate of patients invited into the program,
  2. Eradication rate of infection with H. pylori,
  3. Description of adverse events profile.
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### **Data analysis plan**

1. Participation rate of patients invited into the program: descriptive calculation of rates.

2. Eradication rate of infection with H. pylori: descriptive calculation of rates.
3. Adverse events profile: qualitative (and descriptive) analysis.

## Data management

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Unknown

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### Check completeness

Unknown

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### Check stability

Unknown

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**Check logical consistency**

Unknown

**Data characterisation**

**Data characterisation conducted**

Not applicable