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

Study ID

1000000144

DARWIN EU® study

No

Study countries

- Croatia
- Ireland
- Latvia
- Poland
- Romania
- Slovenia

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.

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

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Study contact

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Primary lead investigator

Bojan Tepeš

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/02/2023

Study start date

Planned: 01/02/2024

Actual: 04/03/2024

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

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Data collection methods:

Primary data collection

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).

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

AMOXICILLIN
BISMUTH
LEVOFLOXACIN HEMIHYDRATE
METRONIDAZOLE
TETRACYCLINE

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

Medical condition to be studied

Helicobacter infection

Population studied

Age groups

- Adults (18 to < 46 years)

Estimated number of subjects

6.800

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.

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Not applicable