Prevention of gastric cancer by eradication of Helicobacter pylori infection

First published: 27/10/2023

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Study Finalised

Administrative details

EU PAS number

EUPAS107327

Study ID

108428

DARWIN EU® study

No

Study countries

Slovenia

Study description

The main goal of this observational study is to assess the feasibility of implementing the proposed "test-and-treat" screening program. The program has been proposed for an active infection with Helicobacter pylori (H. pylori) to

prevent the development of gastric cancer in patients between 30-34 years of age. Patients will be randomly selected from a pool of potential respondents and invited to participate in the study by the chosen personal physician's registered nurse. Those patients who will provide their informed consent to participate will take an interview with a registered nurse about childhood risk factors and their habits regarding the consumption of alcohol and use of tobacco. Moreover, all participating patients will have serology taken to test on the presence of H. pylori antibodies. Patients with a positive serological test will take a confirmatory urea breath test (UBT) to diagnose them with a potential active infection with H. pylori. Patients with a confirmed active infection with H. pylori will be treated by bismuth-based quadriple therapy and the success of eradication will be tested by taking a second UBT during a control check-up. Patients with a positive result of the second UBT will be treated once more by a modified bismuth-based quadriple therapy, and the success of eradication will be retested by a third UBT during a second control check-up. Compliance to testing and treatment, the treatment results, adverse effects and reasons for dropping out of participation will be monitored for each of the participants. Research reports will be disseminated and results will be presented to the public and scientific community to foster future developments in gastric cancer prevention.

Study status

Finalised

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

Actual: 12/10/2022

Study start date

Planned: 04/12/2023

Actual: 01/02/2024

Date of final study report

Planned: 31/12/2026

Actual: 30/04/2025

Sources of funding

- EU institutional research programme
- Other

More details on funding

Ministry of Health, HaDEA: Eu4Health programme

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

Scope of the study:

Effectiveness study (incl. comparative)

Evaluation of patient-reported outcomes

Feasibility analysis

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The main objective of this observational study is to assess the feasibility of implementing the proposed "test-and-treat" screening program.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Bizmutov oksid Krka 120 mg film-coated tablets, Emozul 40 mg hard gastroresistant capsules, Nexium 40 mg gastroresistant tablets, Nillar 40 mg gastroresistant tablets, Efloran 400 mg tablets, Tavanic 500 mg film-coated tablets, Fromilid 500 mg film-coated tablets, Amoksicilin Belupo 500 mg dispersible tablets, Hiconcil 500 mg hard capsules

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Medical condition to be studied

Helicobacter infection

Population studied

Age groups

- Adults (18 to < 46 years)

Estimated number of subjects

2.000

Study design details

Setting

Community Healthcare Center Dr. Adolf Drolc Maribor

Outcomes

1.Feasibility and acceptability of the proposed practical implementation of a screening program. 2. Participation rate of patients invited into the program, 3. Eradication rate of infection with H. pylori, 4. Description of adverse events profile, 5. Associations between patient-reported outcomes and the results of test-and-treat strategy.

Data analysis plan

Analytical methods will depend on the type of research question: 1.Feasibility and acceptability of the proposed practical implementation of a screening program: qualitative questionnaire following the structure of TELOS framework. 2.Participation rate of patients invited into the program: descriptive calculation of rates. 3. Eradication rate of infection with H. pylori: descriptive calculation of rates. 4. Adverse events profile: qualitative (and descriptive) analysis. 5. Associations between patient-reported outcomes and the results of test-and-treat strategy: correlation analysis, chi-square test, odds ratio (or relative risk).

Documents

Study publications

ABSTRACT Background Most gastric cancer cases are attributable to chronic H...

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.

Data sources

Data sources (types)

Other

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

No