Prevalence of multidrug resistant micro-organism carriage in patients undergoing an ERCP in four different countries

Published: 14-12-2021
Last updated: 06-05-2024

The primary aim of the study is to assess the prevalence of MDRO carriage in patients undergoing ERCPs. This will be performed in four different countries with expected significantly different prevalence rates of MDRO carriage, namely: India, United...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON50359

Source
ToetsingOnline

Brief title
The PREVENT study

Condition

- Hepatic and hepatobiliary disorders
- Hepatobiliary neoplasms malignant and unspecified

Synonym
Duodenoscope associated infections

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Boston Scientific Cooperation

International,Boston Scientific International

Intervention

Keyword: Bacterial / drug effects, Cholangiopancreatography, Drug Resistance, Endoscopic Retrograde, Multiple, Prevalence

Outcome measures

Primary outcome

The prevalence of MDRO's in patients undergoing ERCP in four different

countries: Italy, the Netherlands, United States and India.

Secondary outcome

- To identify risk factors that predict MDRO carriage.

- Prevalence of contamination of duodenoscopes in a Dutch tertiary care setting.

- If the presence of MDRO in the rectal and nasal/throat E-swabs predicts the

presence of MDRO in the duodenum.

- What is the composition of the duodenal microbiome of patients undergoing an

ERCP.

- What is the composition of the rectal microbiome of patients undergoing an

ERCP

- What is the incidence of duodenoscope-associated colonization and infection

in patients who have been treated with a colonized duodenoscope.

Study description

Background summary

Over the last two decades it has become clear that one of the risks of endoscopic retrograde cholangiopancreatography (ERCP) is transmission of microorganisms through contaminated re-usable duodenoscopes. This is especially

of concern when this involves multidrug resistant microorganisms (MDRO). Transmission of MDRO by contaminated re-usable duodenoscopes to multiple patients is now increasingly encountered. Since these re-usable instruments cannot be sterilized, they require an extensive, and unfortunately error prone, reprocessing technique. Despite several efforts to overcome this problem, new outbreaks are still being reported and new reprocessing techniques are not capable of producing a zero contamination rate. Recently, the Food and Drug Administration (FDA) advised manufacturers and health care professionals to transition away from fixed endcap duodenoscopes and instead focus more on the use of duodenoscopes with disposable components or fully disposable duodenoscopes. Single use duodenoscopes completely eliminate the risk of becoming infected or colonized by microorganisms originating from other patients. However, a complete transition towards disposable duodenoscopes requires a huge investment. Whether this investment outweighs the risk of contamination depends on the prevalence of MDRO and the risk of duodenoscope-associated infections (DAI). However, there is no known prevalence of MDRO in patients undergoing ERCP and the risk of DAI is not known.

Study objective

The primary aim of the study is to assess the prevalence of MDRO carriage in patients undergoing ERCPs. This will be performed in four different countries with expected significantly different prevalence rates of MDRO carriage, namely: India, United States, Italy and the Netherlands. The MDRO included in this study are Carbapenemase-producing Enterobacterales (CPE), Carbapenemase-producing Pseudomonas (CPP), Extended spectrum Beta Lactamase-producing Enterobacterales (ESBL), Vancomycin-resistant Enterococci (VRE) and Methicillin-resistant Staphylococcus aureus (MRSA).

Secondary questions include: Only for the cohort from the Netherlands
- To identify risk factors that predict MDRO carriage.
- Prevalence of contamination of duodenoscopes in a Dutch tertiary care setting.
- If the presence of MDRO's in the rectal and nasal/throat E-swabs predicts the presence of MDRO's in the duodenum.
- What is the composition of the duodenal microbiome of patients undergoing an ERCP.
- What is the composition of the rectal microbiome of patients undergoing an ERCP.
- What is the incidence of duodenoscope-associated colonization and infection in patients who have been treated with a colonized duodenoscope.

Study design

Prospective observational multi-center study

Study burden and risks

Patients will be asked to fill in a questionnaire about the risk factors of MDRO-carriage, this is minimally burdensome. A throat/nose swab will be taken prior to the ERCP. This is completely safe, and can be taken with minimal discomfort. After the patient has been sedated, two rectal E-swabs will be taken before the start of the ERCP. This is also negligibly risky and the patient does not experience any discomfort because of the sedation.

In the Netherlands, a small amount of duodenal fluid will be aspirated through a sterile catheter during the ERCP procedure. The collection of the fluid is non-invasive and negligibly risky, prolonging the ERCP duration to a minimum. The patient does not experience any discomfort from this action.

In the Netherlands, if patients have been treated with a duodenoscope colonized with oral or gastrointestinal flora, they will be requested to collect some feces at home and send/or bring this to the laboratory.

There are no benefits for patients from participating in this study.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- The subject is planned to undergo an ERCP procedure, either through an outpatient department or an inpatient department
- The subject is >= 18 years old
- The subject is capable to understand the information required to give informed consent

Exclusion criteria

- In case the inclusion criteria were not met

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-01-2022
Enrollment:	343
Type:	Actual

Ethics review

Approved WMO Date:	14-12-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-01-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-04-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-04-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL79136.078.21