The effect of a single gift antibiotics before ERCP to prevent post-ERCP pancreatitis.
A study protocol for a single centre, double blinded randomized controlled study.

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This study aims to further reduce the incidence of a post-ERCP pancreatitis by administrating a single gift antibiotics after the procedure.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49650

Source
ToetsingOnline

Brief title
ERCP AB

Condition

- Other condition

Synonym
infection of pancreas, pancreatitis

Health condition

pancreatitis na ERCP

Research involving
Human

Sponsors and support

Primary sponsor: Elisabeth-Tweesteden ziekenhuis
Source(s) of monetary or material Support: eigen vakgroep MDL (stichting innovatie en kwaliteit MDL)

Intervention

Keyword: Antibiotics, ERCP, pancreatitis, prevention

Outcome measures

Primary outcome

Primary study parameter is the incidence of post-ERCP pancreatitis the day

after the ERCP. Post-ERCP pancreatitis will be defined as the presence of

abdominal pain and an increased lipase according to the Cotton criteria.

Delayed post-ERCP pancreatitis will be assessed until 4 weeks after the

procedure.

Secondary outcome

see primary study parameters

Study description

Background summary

An acute pancreatitis is the most common and severe complication of an endoscopic retrograde cholangiopancreatography (ERCP). Despite standard non-steroidal anti-inflammatory drug (NSAID) post-ERCP pancreatitis prophylaxis, still a significant number of patients develop a pancreatitis The results of previous studies showed that antibiotics before or after the procedure also reduces the risk of post-ERCP pancreatitis.

Study objective

This study aims to further reduce the incidence of a post-ERCP pancreatitis by administrating a single gift antibiotics after the procedure.

Study design

The study is a single centre, double blinded randomized controlled trail. It will be conducted at the Elisabeth-TweeSteden Hospital Tilburg. Every participant will receive the standard post-ERCP pancreatitis prophylaxis, diclofenac before the procedure. Participants will be randomized to an intervention group who will receive a single gift antibiotics intravenous and a control group who will receive placebo before the ERCP. Patients and investigators will be blinded for the intervention.

Intervention

The intervention group receives 2 gram ceftazidim solution in a 10ml syringe intravenous before the ERCP. The control group receives sodium chloride (NaCl) in a 10ml syringe intravenous before the ERCP.

Study burden and risks

The patients who participate in the study have to undergo an ERCP and will receive standard NSAIDS prophylaxis before the procedure. In this study patients receive additional a single gift ceftazidim or NaCl. Antibiotics is already standard care in some hospitals to prevent post-ERCP pancreatitis. Because, it is only an one-time gift antibiotics the additional risks related to the study are negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Patients undergoing an elective ERCP at the Elisabeth-TweeSteden hospital Tilburg, who are willing to participate and give informed consent.
• Have the minimum age of 18 years or older.

Exclusion criteria

• Patients who experience a chronic or acute pancreatitis.
• Patients with known pancreas malignancy.
• Patients treated with antibiotics/ cholangitis.
• Patients with any contraindication or with a known allergy to ceftazidime or to any other cephalosporin antibiotics.
• History of severe hypersensitivity (e.g. anaphylactic reaction) to any other type of beta-lactam antibacterial agent (penicillins).
• Patients who are pregnant, lactating or planning pregnancy while enrolled in the study.
• Patients who are unsuitable for inclusion in the study in the opinion of the investigator for any reason that may compromise the subject*s safety or confound data interpretation.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	05-01-2021
Enrollment:	500
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ceftazidim
Generic name:	ceftazidim
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	24-08-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-08-2021
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22878
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2020-000572-37-NL
CCMO	NL72967.028.20

Study results

Date completed: 03-12-2024

Actual enrolment: 155

Summary results
Trial ended prematurely