ERCP- Antibiotics study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22878

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Post-ERCP pancreatitis

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

The incidence of post-ERCP pancreatitis. Post-ERCP pancreatitis being defined as the presence of abdominal pain and an increased lipase.

Secondary outcome

Incidence of delayed post-ERCP pancreatitis until four weeks after the procedure. Assessment which subgroup of patients are at risk of developing a Post-ERCP pancreatitis or which

subgroup benefit from an additional gift antibiotics to reduce the post-ERCP pancreatitis incidence. Assessment of other post-ERCP complications, such as cholangitis, septicemia, and bacteremia.

Study description

Background summary

An acute pancreatitis is the most common and severe complication of an endoscopic retrogade cholangiopancreatography (ERCP). Despite the currently used non-steroidal anti-inflammatory drug (NSAID) prophylaxis, a significant number of patients develop a pancreatitis. The aim of this study is to further reduce the incidence of a post-ERCP pancreatitis (PEP) by administrating a single gift antibiotics before the procedure.
This study is a single centre, double blinded randomized controlled trial. Subjects will receive, according to randomisation, either antibiotics or placebo addiotional to the NSAID before the ERCP procedure.

Study objective

Ceftazidim as prophylaxis to reduce the incidence of Post-ERCP pancreatitis.

Study design

Week -2, visit 0 (before ERCP), visit 1 (withing 24 hours after procedure), visit 3 (4 weeks after discharge)

Intervention

Ceftazidim or placebo (NaCl 0,9%/10mL)

Contacts

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Eligibility criteria

Inclusion criteria

- Patients undergoing an elective ERCP at the Elisabeth-TweeSteden hospital in 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:	Other
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-01-2021
Enrollment:	500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-05-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49650
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9453
CCMO	NL72967.028.20
OMON	NL-OMON49650

Study results