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Prevention of complications after endoscopic retrograde cholangio-pancreaticography using the antihypertensive drug Cozaar®

Submission date 13/11/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/01/2010	**Overall study status** Completed	
Last Edited 19/05/2022	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2005-004545-34

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial of the angiotensin II receptor blocker losartan (Cozaar®) in the prevention of hyperenzymemia after endoscopic retrograde cholangio-pancreaticography (ERCP)

Study objectives
Angiotensin II receptor type 1 blocker prevents post-endoscopic retrograde cholangio-pancreaticography (ERCP) pancreatitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethical Committee in Stockholm approved on the 12th January 2005 (ref: 2005/1278-31 /2)

Study design
Triple blinded randomised placebo-controlled multicentre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Post-endoscopic retrograde cholangio-pancreaticography pancreatitis

Interventions
Patients are randomised to placebo or 50 mg losartan (Cozaar®) given orally one hour before ERCP. The interventions are given once only; planned follow up is 24 hours.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Losartan (Cozaar®)

Primary outcome measure
Hyperenzymemia (amylase and or lipase) 24 hours after ERCP

Secondary outcome measures
1. Pancreatitis after ERCP defined as abdominal pain persisting more than 24 hours after ERCP and hyperenzymemia defined as three times the upper normal limit
2. Pain measured by the visual analogue scale (VAS) (0 = no pain, 10 = unbearable pain) pre-ERCP and 24 hours after ERCP

Overall study start date
01/04/2006

Completion date
31/10/2008

Eligibility

Key inclusion criteria
1. Patients above 18 years of age, either sex
2. ERCP indicated for diagnostic or therapeutic reasons
3. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Previous ERCP within one year
2. Current elevation of pancreatic amylase and lipase
3. Ongoing acute or chronic pancreatitis
4. Current use of any angiotensin I converting enzyme (ACE) inhibitor or angiotensin II type 1 receptor blocker
5. Bilateral renal artery stenosis or unilateral in case of a single kidney
6. Known hypersensitivity to angiotensin II type 1 receptor blockers

7. Pregnancy
8. Breastfeeding
9. Predefined severe disease (e.g. ongoing sepsis, disseminated intravascular coagulopathy, acute circulatory collapse, severe dehydration, hypovolaemia, severe renal insufficiency or severe liver failure)

Date of first enrolment
01/04/2006

Date of final enrolment
31/10/2008

Locations

Countries of recruitment
Sweden

Study participating centre
Upper Gastrointestinal Research Group (UGIR)
Stockholm
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Sponsor information

Organisation
Karolinska Institutet (Sweden)

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Sponsor type
Research organisation

Website
http://ki.se/ki/jsp/polopoly.jsp?d=130&l=sv

ROR

https://ror.org/056d84691

Funder(s)

Funder type
Research organisation

Funder Name
Swedish Society of Medicine (Sweden)

Funder Name
Lisa and Johan Grönberg Foundation (Sweden)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		05/02/2021	19/05/2022	No	No