ISRCTN46556454 https://doi.org/10.1186/ISRCTN46556454

Does prophylactic administration of magnesium reduce the risk and severity of post-endoscopic retrograde cholangiopancreatography (post-ERCP) pancreatitis? A clinical study.

Submission date
01/03/2009

Registration date
07/04/2009

Last Edited
12/02/2013

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Magnesium sulphate in the prevention of Post-ERCP Pancreatitis: a prospective randomised, placebo-controlled multicentre study

Acronym
MagPEP

Study objectives
Acute pancreatitis is the most common complication of diagnostic and therapeutic endoscopic retrograde cholangiopancreatography (ERCP). Despite continuing research, no pharmacologic substance capable of effectively reducing the incidence of this complication has found its way into clinical routine.

A number of experimental observations suggest that pancreatic calcium concentrations play an important role in the initiation of pancreatic protease activation, the first step in the course of acute pancreatitis. Magnesium can act as a calcium-antagonist and counteract several effects in the calcium signal transduction pathway. It can thereby attenuate premature intracellular activation of proteolytic digestive enzymes in the pancreas and thus reduce the severity of pancreatitis.

Preliminary experiments have shown that magnesium (Mg2+) therapy administered as a food supplement in an animal model of acute pancreatitis has a beneficial effect on the course of the disease. We therefore hypothesise that the administration of magnesium sulphate before and after diagnostic or therapeutic endosopic retrograde cholangiopancreatography reduces the risk and severity of post-ERCP.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board at the Medical Faculty of the Ernst-Moritz-Arndt-University of Greifswald, Germany, gave approval on the 30th October 2008 (ref: BB 92/08)

Study design
Prospective randomised double-blind placebo-controlled multicentre study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-ERCP pancreatitis

Interventions
Magnesium arm:
Intravenous application of 500 ml NaCl 0.9% containing 10 ml magnesium sulphate 50% (= 4930 mg magnesium sulphate heptahydrate; magnesium content: 486.1 mg = 20 mmol = 40 mval) 30 minutes before and 6 hours after ERCP. Duration of each intravenous infusion: 30 minutes.

Placebo arm:
Intravenous application of 500 ml NaCl 0.9% + 10 ml NaCl 0.9% 30 minutes before and 6 hours after ERCP. Duration of each intravenous infusion: 30 minutes.

Follow up:
1. 6 and 24 hours after ERCP: blood samples, clinical examination, pain assessment, documentation of pain medication
2. If post-ERCP pancreatitis occurs: daily blood samples, clinical examination, pain assessment and documentation of pain medication until discharge from the hospital
3. 30 days after ERCP: telephone follow-up questionnaire

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Magnesium sulphate

Primary outcome(s)
Reduction of the incidence of post-ERCP pancreatitis by 50%

Key secondary outcome(s))
1. Intake of analgesics
2. Duration of hospital stay in days
3. Lipase levels measured 6 and 24 hours after ERCP
4. 30-days mortality as measured with the EQ-5D-questionnaire in the telephone interview 30 days after ERCP

Completion date
30/11/2009

Eligibility

Key inclusion criteria
1. Adult (greater than or equal to 18 years of age) patients (male and female) with a medical indication for a diagnostic or therapeutic endoscopic retrograde cholangiopancreatography (ERCP)
2. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Known allergy or intolerance to one of the medicaments utilised in the study or their ingredients
2. Participation in another clinical study during the previous four weeks
3. Pregnancy or breast feeding
4. Acute pancreatitis
5. Renal insufficiency greater than or equal to stadium 4 (National Kidney Foundation Disease Outcomes Quality Initiative™ [NKF KDOQI™])
6. Hyperthyroidism
7. Symptomatic bradycardia less than 35 bpm
8. Atrioventricular block greater than 1° or other cardial conduction defects
9. Myasthenia gravis
10. Liver cirrhosis Child C
11. Any apparent coagulopathy
12. Kidney stone diathesis (calcium-magnesium-ammonium-phosphate stones)
13. Mental impairment, addictive or other disorders leading to the patients inability to understand the scope and possible consequences of a participation in the clinical trial
14. Magnesium medication within 14 days before the procedure
15. Inability to give informed consent

Date of first enrolment
01/06/2009

Date of final enrolment
30/11/2009

Locations

Countries of recruitment
Germany

Study participating centre
Klinik für Innere Medizin A
Greifswald
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17475

Sponsor information

Organisation
University Hospital Greifswald (Germany)

ROR
https://ror.org/025vngs54

Funder(s)

Funder type
Research council

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany) (ref: SA 1994/1-1)

Funder Name
Ernst Moritz Arndt University of Greifswald (Ernst-Moritz-Arndt-Universität Greifswald) (Germany) - Department of Medicine A

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/01/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes