

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	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/04/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/02/2013	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.pancreas.de/>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 endoscopic 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Can be found at <http://www.pancreas.de> (German only)

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 measure

Reduction of the incidence of post-ERCP pancreatitis by 50%

Secondary outcome measures

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

Overall study start date

01/06/2009

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

502 patients

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 cardiac 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

Germany

17475

Sponsor information

Organisation

University Hospital Greifswald (Germany)

Sponsor details

c/o Administrative Director Gunter Gotal

Fleischmannstrasse 8

Greifswald

Germany

17475

Sponsor type

Hospital/treatment centre

Website

<http://www.klinikum.uni-greifswald.de/>

ROR

<https://ror.org/025vn54>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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