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Predrainage administration of Dopamine in the Renal function of selected patients with Obstructive Jaundice

Submission date	Recruitment status	[ ] Prospectively registered
08/01/2010	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
15/01/2010	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
15/01/2010	Digestive System	[ ] 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
Predrainage administration of dopamine associated with fluid administration improved renal function in selected patients with obstructive jaundice: a prospective randomised study

Acronym

DROJ

Study objectives
No studies have been carried out to evaluate the effects of dopamine in obstructive jaundice (OJ) patients on the renal and endocrine derangements observed in these patients before biliary drainage or surgery. The present study was therefore designed to analyse the effect of dopamine associated with fluid administration on extracellular water (ECW), water and sodium regulating hormones and renal function alterations in patients with OJ undergoing endoscopic internal biliary drainage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hospital Reina Sofia Clinical Trials and Ethics Committee approved in March 2005 (ref: PIO-20155)

Study design
Prospective randomised controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obstructive jaundice

Interventions
Two treatment groups were created according to whether patients received dopamine at 3 mg /Kg/min or not, associated with 3000 ml of saline solution for 48 hours before biliary drainage in addition to their regular hospital ward diet. For the post-drainage study, patients treated with dopamine prior to biliary drainage, will be randomised according to whether they continue with dopamine for 72 hours or not. All patients will be kept under the same conditions. After endoscopic internal drainage, patients will fast for the first 12 hours and 2500 ml of glucosaline solution containing 150 mEq of NaCl will be administrated until the following morning. On the second day, the intravenous infusion will be stopped and patients will receive a 2000 kcal/day diet for up to 72 hours when the study protocol will finish. Billiary drainage is considered successful if total bilirubin decreases by at least 30% and aerobilia with reduction of the common bile duct diameter demonstrated by ultrasound 72 hours after the procedure.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dopamine

Primary outcome(s)
Renal function (CrCl), assessed at admission, before drainage, as well as 24 hours and 72 hours after biliary drainage.

Key secondary outcome(s))
Assessed at admission, before drainage, as well as 24 hours and 72 hours after biliary drainage:
1. Extracellular water (ECW) volume
2. Serum leves of aldosterone, renin, atrial natriuretic peptide (ANP), antidiuretic hormone (ADH), endothelin-1 (ET-1)
3. Urine prostaglandin E2 (PgE2)

Completion date
21/06/2009

Eligibility

Key inclusion criteria
1. Malignant OJ with serum bilirubin higher than 6 mg/dl
2. Ultrasound evidence of extrahepatic and intrahepatic bile duct dilation (more than 8 mm and 4 mm respectively)
3. Feasibility of internal endoscopic biliary drainage
4. Aged 35 to 76 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Cholangitis
2. Acute pancreatitis
3. Heart disease
4. Arterial hypertension
5. Chronic lung disease
6. Use of diuretics
7. Chronic renal failure

Date of first enrolment
10/01/2007

Date of final enrolment
21/06/2009

Locations

Countries of recruitment
Spain

Study participating centre
Imperio Argentina 43
Cordoba
Spain
14014

Sponsor information

Organisation
Reina Sofia University Hospital (Spain)

ROR
https://ror.org/02vtd2q19

Funder(s)

Funder type
Government

Funder Name
Spanish Ministry of Health (Spain) - Health Research Fund (Fondo de Investigaciones Sanitarias [FIS]) (ref: PIO-20155)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration