

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

Submission date 08/01/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/01/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/01/2010	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

Contact information

Type(s)

Scientific

Contact name

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Contact details

Imperio Argentina 43
Cordoba
Spain
14014

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

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

Secondary outcome measures

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)

Overall study start date

10/01/2007

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

Age group

Adult

Sex

Both

Target number of participants

100

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)

Sponsor details

Avda. Menéndez Pidal S/N

Cordoba

Spain

14004

Sponsor type

Hospital/treatment centre

Website

<http://www.juntadeandalucia.es/servicioandaluzdesalud/hrs2/>

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

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