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Extracellular vesicles and biliary stenoses

Submission date	Recruitment status	[_] Prospectively registered
31/01/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/02/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/07/2018	Digestive System	

Plain English summary of protocol

Background and study aims
Bile is a substance produced by the liver and stored in the gall bladder, which is secreted into the small intestine to help digest fats from the diet. Common bile duct stenosis is the narrowing of the bile duct which blocks bile from being released, leading to problems with digestion. This condition can be malignant (cancerous) or benign (non-cancerous), but this is very hard to determine and can only be done reliably through surgery. It is important to determine this as malignant bile duct stenosis could be a sign of pancreatic cancer. Studies have shown that cancer cells release more extracellular vesicles (EVs) (packages released by cells that surround the membrane) as compared to healthy cells. It is estimated that using EVs as a marker for malignancy through measuring specific markers found in the tissue can help differentiate between malignant and benign stenosis. This study aims to determine if the measurement of EV concentration in bile could improve determining between malignant and benign common bile duct stenosis.

Who can participate?
Adults over the age of 16 who require their bile duct to be unblocked (biliary catheterization)

What does the study involve?
Participants have their bile duct unblocked through an endoscopic procedure (a long thin tube that has a light and a camera inserted through a small incision) which uses a catheter (a long thin tube), that is inserted through a small incision in the abdomen, into the bile duct area to remove bile. Bile samples are taken and are sent to a laboratory for analysis. Participants are followed up for one year to make sure they do not have malignant bile duct stenosis.

What are the possible benefits and risks of participating?
There are no direct benefits or risks to participants.

Where is the study run from?
Geneva University Hospital (Switzerland)

When is the study starting and how long is it expected to run for?
August 2006 to December 2015

Who is funding the study?
Geneva University Hospital (Switzerland)

Who is the main contact?
Jean Louis Frossard
jean-louis.frossard@hcuge.ch

Contact information

Type(s)
Scientific

Contact name
Prof Jean Louis Frossard

Contact details
Service of Gastroenterology and Hepatology, Geneva University Hospitals
Genève
Switzerland
1211

Additional identifiers

Study information

Scientific Title
Extracellular vesicles in human bile as a novel and accurate marker of malignant biliary stenoses

Study objectives
This study aims to determine if the measurement of EV concentration in bile could improve the clinical discrimination between malignant and nonmalignant CBD stenosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethical Committee Geneva,08/08/2006, ref: GE 04-091
2. Ethical Committee Université libre de Bruxelles, Erasmus Hosptial, 02/11/2009, ref: P2009 /007, CCB B 40620095782

Primary study design
Observational

Study design
Observational multi-center longitudinal case-control study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Common bile duct stenosis

Interventions
Participants undergo a biliary catheterization through endoscopic exploration of the biliary tract. This involves bile being removed from the common bile duct after it has been aspirated. Bile is aliquoted into eppendorf tubes (5ml) and frozen to -20 °C and stored at a laboratory in Geneva. The bile samples examined through laboratory analysis for markers of malignant and nonmalignant common bile duct stenosis.

The first ten consecutive patients are assigned to the discovery cohort together with ten bile duct stones patients (i.e., internal controls proven nonmalignant) before endoscopy. The remaining 30 patients are assigned to the verification cohort before endoscopy is performed. Final diagnosis is determined by pathological examination of tissue sample in all patients with common bile duct stenosis.

Participants are are clinically followed up for 1 year to show no sign of malignancy with a common bile duct stenosis related to chronic pancreatitis. Follow up will include clinical history with patient interview, measurement of CA-19.9 and imaging modalities. For bile duct stone patients, the diagnosis is based on radiological and endoscopic features.

Intervention Type
Other

Primary outcome(s)
1. Extracellular vesicles (EVs) are evaluated by transmission electron microscope (TEM) and nanoparticle tracking analysis (NTA) and through medical interviews at baseline and 12 months
2. Serum bilirubin and CA19.9 are measured in all patients at baseline

Key secondary outcome(s)
Performance of extracellular vesicles (EVs) is assessed through tumor markers (including CA19-9) at baseline

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Patients scheduled for biliary catheterism due to obstructive jaundice or cholestasis of biliary origin (suspicion of cancer, suspicion of stones, chronic pancreatitis)
2. Age > 16 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Key exclusion criteria
1. Less than 16 years old
2. Pregnant women

Date of first enrolment
02/11/2009

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Belgium

Switzerland

Study participating centre
Service of Gastroenterology and Hepatology
Geneva University Hospital
R G Perret Gentil 14
Genève
Switzerland
1211

Study participating centre
Service of Gastroenterology
Erasme University Hospital
Route de Lennik 808
Brussels
Belgium
10170

Sponsor information

Organisation
Service of Gastroenterology and Hepatology

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Not defined

Funder Name
Geneva University Hospital

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Jean Louis Frossard (jean-louis.frossard@hcuge.ch).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2017		Yes	No