

Extracellular vesicles and biliary stenoses

Submission date 31/01/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/02/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/07/2018	Condition category Digestive System	<input type="checkbox"/> Individual participant data

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
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Contact information

Type(s)
Scientific

Contact name
Prof Jean Louis Frossard

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
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 Hospital, 02/11/2009, ref: P2009/007, CCB B 40620095782

Study design

Observational multi-center longitudinal case-control study

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 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 measure

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

Secondary outcome measures

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

Overall study start date

08/08/2006

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

Age group

Adult

Sex

Both

Target number of participants

50 in total. 20 for the discovery part of the study and 30 for the confirmation cohort

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

Sponsor details
Geneva University Hospital
R G Perret Gentil 14
Genève
Switzerland
1211

Sponsor type
Hospital/treatment centre

Website
www.hcuge.ch

ROR
<https://ror.org/01m1pv723>

Funder(s)

Funder type
Not defined

Funder Name
Geneva University Hospital

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal by end of 2017.

Intention to publish date

31/12/2017

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