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Ischaemic preconditioning in liver resections studied with microdialysis

Submission date 09/02/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/03/2009	**Overall study status** Completed	
Last Edited 09/12/2009	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Ischaemic preconditioning in liver resections studied with microdialysis: a randomised single-blinded single-centre controlled trial

Study objectives
Does ischaemic preconditioning before 15/5 Pringles manoeuvre change metabolism or ischaemia-reperfusion injury compared to 15/5 Pringles manoeuvre alone in surgical liver resections?

As of 09/12/2009 this record has been updated to the actual end date of trial recruitment - the initial anticipated end date for this trial was 30/04/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional ethics committee in Linköping Sweden gave approval in June 2006 (ref: M100-06)

Study design
Randomised single-blinded single-centre controlled trial

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
Liver tumour

Interventions
All patients will receive intrahepatic microdialysis catheters intra-operatively. Pringle manoeuvre means closure of the portal pedicle. The treatment arm will begin surgery with 10 minutes of Pringle and then 10 minutes of reperfusion (i.e. ischaemic preconditioning) will be allowed before regular 15 minutes of ischaemia and 5 minutes of reperfusion in cycles until the transsection is finished.

The control arm will not have preconditioning, otherwise Pringle will be used in the same manner.

Both arms are followed for 5 days post-operatively with microdialysis and laboratory testing and then a follow-up visit is held at the outpatient clinic about 30-days post-operatively where complications and pathological diagnosis is documented.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Changes in metabolism (anaerobic/aerobic), studied with microdialysis
2. Ischaemia-reperfusion injury (histology, myeloperoxidase [MPO], etc)

Results of the microdialysis samples are recorded continuously for 5 days post-operatively (and blood samples daily for 5 days), but data are not compiled and analysed until the last study participant has completed the 30-day follow-up time.

Secondary outcome measures
Extent of the resected liver volume, recorded continuously and the volume of resection will be recorded immediately after the operation. Data are not compiled and analysed until the last study participant has completed the 30-day follow-up time.

Overall study start date
01/02/2008

Completion date
21/09/2009

Eligibility

Key inclusion criteria
1. Aged greater than 17 years of age (either sex)
2. Suspected malignant tumour in the liver
3. Assigned to curative liver resection of more than one liver segment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
32

Key exclusion criteria

1. Synchronous resection of another hollow viscus
2. Jaundice (bilirubin greater than 60 mM)
3. Ongoing infection
4. Child's B or worse

Date of first enrolment
01/02/2008

Date of final enrolment
21/09/2009

Locations

Countries of recruitment
Sweden

Study participating centre
Department of Surgery
Linköping
Sweden
581 85

Sponsor information

Organisation
The Bengt Ihre Foundation (Sweden)

Sponsor details
Swedish Society of Medicine
Box 73
Stockholm
Sweden
101 35

Sponsor type
Charity

Website
http://www.sls.se/svls.cs

Funder(s)

Funder type

Research council

Funder Name
The Health Research Council of South-East of Sweden (FORSS Sydöstra sjukvårdsregionen) (Sweden)

Funder Name
The Bengt Ihre Foundation (Sweden) - through the Swedish Society of Medicine

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