

Ischaemic preconditioning in liver resections studied with microdialysis

Submission date 09/02/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/03/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/12/2009	Condition category Cancer	<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
Dr Anders Winbladh

Contact details
Department of Surgery
University Hospital
Linköping
Sweden
581 85

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 transection 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