Oslo CoMet study: What and why

OSlo Laparoscopic vs. Open resection of METastases study.

- Clinicaltrials.gov id: NCT01516710
- Regional ethical approval after dedicated meeting with committee

- “Is randomization really necessary?”
- “Yes, and it’s now or never”
Oslo CoMet-study: End point

- Primary end point (n=254)
  - 30 d morbidity (Accordion)
  - Reduction in morbidity from 27% to 13%
  - Inclusion 2012-2015
Oslo CoMet-study: Preop workup

• CT chest/abdomen (venous)

• MRI liver
  – Diffusion
  – Hepatocyte-specific contrast

• Standard lab tests
Oslo CoMet-study: Inclusion criteria

• Resectable colorectal liver metastases
  – Resectable lung and adrenal mets allowed

• Parenchyma sparing liver resection
  – up to 3 segments

• Exclusion criteria:
  – Need for
    • Left or right formal hepatectomy
    • Reconstruction of vessels or bile ducts
    • Ablation in addition to resection
Several studies on one population

**Study 1: Immune response**
- A comparison of the inflammatory response in the first 45 patients included in the study (cytokine, chemokine and complement activation)

**Study 2: Tumor biology**
- Establishment of a bio bank for molecular analysis of tumour tissue.
- Linking of genome data to clinical information provides an opportunity for identifying prognostic factors.

**Study 3: Health economy**
- A health economy evaluation of of the two procedures:
  A. in-hospital costs,
  B. 1-year cost/quality of life
  C. lifetime cost (Markov model)

**Study 4: Pain and QoL**
- Pain measurement at 5 postoperative days, 30 days and 120 days
- SF-36 at 30 days, 4 months and 24 months

**Study 5: Imaging**
- Liver specific FDG-PET (respiratory gating)
- CT perfusion of liver

**Study 6: Software development**
- Software for clinical trials
- Focus on integration of all data, including
  - Molecular data from tumors
  - Immunology data

**Study 7: Liver resection map**
- Software for automatic segmentation of liver anatomy and tumors
- Tracing of laparoscopic instruments in model
- Live update of 3D model as the liver changes shape during surgery

**Oslo CoMet-study**
- Randomized controlled trial of open vs laparoscopic liver resection for colorectal metastases
- Planned to include 280 patients
- 165 patients included since Feb. 2012
- Primary end point: 30 d morbidity
The story so far

- From Feb 15\textsuperscript{th} 2012 to Oct 10\textsuperscript{th} 2014:
  - 186 Patients included
  - MDT selects candidates
  - Written consent (outpatient clinic)
  - Computer generated randomization after consent is given
  - Most patients accept
    - Some are referred for laparoscopy (n=3)
    - Patients demand laparotomy (n=3)