Ongoing Clinical Trials
Section Editor: S. Galandiuk, MD, Louisville

This section provides information for researchers on clinical trials being in progress in their field throughout the world. The list of trials described herein is by no means inclusive, and the publisher is not responsible for any data given.

Please use the special questionnaire at the end of this section to submit information on a new trial.

The Ongoing Clinical Trials are only available online, free of charge, under www.karger.com/dsu_issues

Oncology 400
Surgical Infection / Sepsis 404
Miscellaneous 405
Questionnaire for Trial Submission 408
# Ongoing Clinical Trials

This section provides information for researchers on clinical trials being in progress in their field throughout the world. The list of trials described herein is by no means inclusive, and the publisher is not responsible for any data given.

Please use the special questionnaire at the end of this section to submit information on a new trial.

<table>
<thead>
<tr>
<th>Title of Trial</th>
<th>Lead Investigator</th>
<th>Study Design</th>
<th>Current Status</th>
<th>Sponsor</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oncology</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Colorectal</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| CAPP 2                         | Prof. John Burn   | Randomized controlled trial of colorectal polyp and cancer prevention using aspirin and resistant starch in carriers of hereditary nonpolyposis colon cancer (HNPCC) | Data analysis           | MRC, Cancer Research UK, Bayer AG, National Starch and Chemical Company | Ms. Gail Barker
 University of Newcastle, UK | Newcast upon Tyne, UK | Tel.: +44 191 241 8613 E-Mail: gail.barker@ncl.ac.uk |
|                               | University of Newcastle, UK | Phase II, multicenter (33 centers), prospective, double-blind trial |                                                                      |                                                                         |                                                                         |
|                               |                   | Factorial design                                                             |                         |                                                                         |                                                                         |
|                               |                   | Regimen: Aspirin 600 mg, resistant starch 30 g for 2-4 years                 |                         |                                                                         |                                                                         |
|                               |                   | Control: Placebo/active                                                      |                         |                                                                         |                                                                         |
|                               |                   | Endpoint: Colorectal neoplasm                                                |                         |                                                                         |                                                                         |
|                               |                   | Patient population: Gene carriers of hereditary HNPCC n=1000                |                         |                                                                         |                                                                         |
|                               |                   | Data analysis                                                                |                         |                                                                         |                                                                         |
 Erasmus Medisch Centrum Rotterdam, The Netherlands | Tel.: +31 10 463 4735 Fax: +31 10 463 5058 E-Mail: bonjer@hldk.azr.nl |
<p>|                               | Department of Surgery | Multicenter (30 centers), prospective, randomized, open trial               |                         |                                                                         |                                                                         |
|                               | Erasmus Medisch Centrum Rotterdam, The Netherlands | Control: Active controls                                                     |                         |                                                                         |                                                                         |
|                               | Department of Surgery | Endpoint: Locoregional recurrence 3 years postoperative                     |                         |                                                                         |                                                                         |
|                               | Hospital I Clinic, Provincial de Barcelona, Spain | Patient population: Patients with nonmetastatic rectal cancer n=1275       |                         |                                                                         |                                                                         |</p>
<table>
<thead>
<tr>
<th>Title of Trial</th>
<th>Lead Investigator</th>
<th>Study Design</th>
<th>Current Status</th>
<th>Sponsor</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>DaCHS - Prevention of colorectal carcinoma: The role of screening</td>
<td>Prof. Dr. H. Brenner Deutsches Zentrum für Alternsforschung, Heidelberg, Germany</td>
<td>Independent, case-control trial n=1500</td>
<td>Ongoing (start January 2003; end of recruitment December 2007)</td>
<td>DKFZ (Deutsches Krebsforschungszentrum)</td>
<td>Dr. Christoph Seiler, MSc Heidelberg, Germany Tel.: +49 6221 56 6986 Fax: +49 6221 56 6988 E-Mail: <a href="mailto:christoph_seiler@med.uni-heidelberg.de">christoph_seiler@med.uni-heidelberg.de</a> <a href="http://www.sdgc.de">www.sdgc.de</a></td>
</tr>
<tr>
<td>Colon-J-pouch versus transverse coloplasty pouch: A randomized controlled trial comparing functional results after rectum resection and different reconstructions</td>
<td>PD Dr. Kaspar Z'graggen Klinik Beau-Site, Berne, Switzerland</td>
<td>Multicenter, prospective, randomized, open trial</td>
<td>Follow-up</td>
<td></td>
<td>Dr. Christoph Seiler, MSc Heidelberg, Germany Tel.: +49 6221 56 6986 Fax: +49 6221 56 6988 E-Mail: <a href="mailto:christoph_seiler@med.uni-heidelberg.de">christoph_seiler@med.uni-heidelberg.de</a> <a href="http://www.sdgc.de">www.sdgc.de</a></td>
</tr>
<tr>
<td>ROMIC: Role of ovarian metastasis in colorectal cancer</td>
<td>R.M.H. Roumen, MD Maxima Medical Center Department of Surgery Veldhoven, The Netherlands</td>
<td>Multicenter (12 centers), prospective, unblinded (oophorectomy) trial</td>
<td>Ongoing (start 2003; end 2007)</td>
<td></td>
<td>R.M.H. Roumen, MD Veldhoven, The Netherlands Tel.: +31 40 8888 556 Fax: +31 40 8888 565 E-Mail: <a href="mailto:r.roumen@mmc.nl">r.roumen@mmc.nl</a></td>
</tr>
<tr>
<td>Title of Trial</td>
<td>Lead Investigator</td>
<td>Study Design</td>
<td>Current Status</td>
<td>Sponsor</td>
<td>Contact</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------</td>
<td>---------------------------------------------------</td>
<td>----------------------</td>
<td>--------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Influence of two different resection techniques of liver metastases from colorectal cancer on hematogenous tumor cell dissemination | Jürgen Weitz, MD Department of Surgery, University of Heidelberg, Germany | Multicenter (3 centers), prospective open trial  
Control: Comparison of two techniques  
Endpoint: Tumor cell detection in blood samples  
Patient population: Patients with liver metastases of a colorectal cancer | Ongoing | Prof. M.W. Büchler | Dr. Christoph Seiler, MSc Heidelberg, Germany  
Tel.: +49 6221 56 6986  
Fax: +49 6221 56 6988  
E-Mail: christoph.seiler@med.uni-heidelberg.de  
www.sdgc.de |
| Pancreatic                                                                   |                                                        |                                                   |                      |                                |                                                                         |
| Primary resection vs. neoadjuvant chemoradiation followed by resection for locally resectable or potentially resectable pancreatic carcinoma without distant metastasis | Prof. Dr. W. Hohenberger University Hospital Erlangen, Germany  
Prof. Dr. G. Grabenbauer University Hospital Erlangen, Germany | Multicenter, prospective, nonrandomized trial  
Patient population: Patients with potentially resectable carcinoma of the pancreatic head  
n=254 (127 per arm)  
Additional information: Pilot project finished, new trial with gemcitabine and cisplatin as radiosensitizers | Ongoing (start June 2003; 55 patients entered to date) |                                | PD Dr. T. Meyer Erlangen, Germany  
Tel.: +49 9131 853 32 96  
Fax: +49 9131 853 65 95  
E-Mail: thomas.meyer@chir.imed.uni-erlangen.de  
PD Dr. T. Brunner Erlangen, Germany  
E-Mail: thomas.brunner@strahlen.imed.uni-erlangen.de |
| ESPAC-3(v2) Adjuvant chemotherapies in resectable pancreatic cancer          | Prof. J.P. Neoptolemos Department of Surgery, University of Liverpool, UK | International multicenter (154 centers) trial; patients with pancreatic ductal adenocarcinoma randomized into one of two groups (gemcitabine; 5-FU and folinic acid; recruitment closed) and patients with ampullary or other tumors of the pancreas randomized into one of three groups (gemcitabine; 5-FU and folinic acid, and observation)  
Endpoint: Overall survival  
Patient population: Patients with resected pancreatic cancer  
n=1030 | Ongoing | Cancer Research UK  
Mrs. Emily Owen, Coordinator Liverpool, UK  
Tel.: +44 151 794 8932  
Fax: +44 151 794 8930  
E-Mail: e.owen@liverpool.ac.uk |
### Ongoing Clinical Trials (continued)

<table>
<thead>
<tr>
<th>Title of Trial</th>
<th>Lead Investigator</th>
<th>Study Design</th>
<th>Current Status</th>
<th>Sponsor</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GEM-CAP</strong></td>
<td>Professor J.P. Neoptolemos</td>
<td>Phase III, multicenter, randomized trial</td>
<td>Ongoing (closed to recruitment as target accrual has been reached)</td>
<td>Ms. Alison Bates, Coordinator &lt;br&gt; Liverpool, UK</td>
<td>Tel.: +44 151 794 8933 &lt;br&gt; Fax. +44 151 794 8930 &lt;br&gt; E-Mail: <a href="mailto:alison.bates@liv.ac.uk">alison.bates@liv.ac.uk</a></td>
</tr>
<tr>
<td>Trial comparing gemcitabine alone or in combination with capecitabine for the treatment of patients with advanced pancreatic ductal adenocarcinoma</td>
<td>Department of Surgery, University of Liverpool, UK</td>
<td><strong>Regimen:</strong> Patients treated with gemcitabine alone or a combination of gemcitabine and capecitabine for 12 weeks; those responding to treatment or with stable disease receive a further 12 weeks of treatment&lt;br&gt; <strong>Primary endpoint:</strong> One-year survival&lt;br&gt; <strong>Secondary endpoint:</strong> Quality of life; median and two-year survival; toxicity; objective response rate&lt;br&gt; <strong>Patient population:</strong> Patients with histological or cytological evidence of locally advanced / metastatic carcinoma of the pancreas not amenable to curative surgery / radiotherapy; n=508</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Miscellaneous</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multicenter randomized trial for laser-induced thermotherapy of colorectal liver metastases</td>
<td>Priv. Doz. C.-T. Germer</td>
<td>Phase III, multicenter (6 centers), randomized trial</td>
<td>Recruitment phase (start August 2000; end July 2007)</td>
<td>BMBF</td>
<td>Prov. Doz. C.-T. Germer &lt;br&gt; Berlin, Germany &lt;br&gt; Tel.: +49 30 8445 2543 &lt;br&gt; Fax: +49 30 8445 2740 &lt;br&gt; E-Mail: <a href="mailto:germer@ukbf.fu-berlin.de">germer@ukbf.fu-berlin.de</a></td>
</tr>
<tr>
<td>Department of Surgery, University Hospital BF Berlin, Germany</td>
<td><strong>Control:</strong> Surgical liver resection&lt;br&gt; <strong>Endpoint:</strong> Patient survival, quality of life/mortality&lt;br&gt; <strong>Patient population:</strong> Patients with 4 or fewer liver metastases, diameter 4 cm or smaller and with no signs of extrahepatic malignant disease; n=400</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Ongoing Clinical Trials

#### Surgical Infection / Sepsis

<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>Investigators</th>
<th>Enrollment</th>
<th>Study Timeline</th>
<th>Funding</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PANTER</strong></td>
<td>Minimally invasive 'step-up approach' vs. maximal necrosectomy in patients with acute necrotizing pancreatitis</td>
<td>Prof. H.G. Gooszen&lt;br&gt;Head, Department of Surgery&lt;br&gt;University Medical Center Utrecht, The Netherlands&lt;br&gt;Chairman Dutch Acute Pancreatitis Study Group</td>
<td>Multicenter (20 centers of the Dutch Acute Pancreatitis Study Group), prospective, non-blinded, active-controlled trial</td>
<td>Ongoing (start January 2006; end January 2009)</td>
<td>The Netherlands Organization for Health Research and Development (ZonMw, grant no. 945-06-910)</td>
<td>Prof. H.G. Gooszen&lt;br&gt;Utrecht, The Netherlands&lt;br&gt;Tel.: +31 30 250 9111&lt;br&gt;Fax: +31 30 253 1944&lt;br&gt;E-Mail: <a href="mailto:h.gooszen@umcutrecht.nl">h.gooszen@umcutrecht.nl</a></td>
</tr>
<tr>
<td><strong>PROPATRIA</strong></td>
<td>Multicenter, randomized, blinded, placebo-controlled trial of probiotic prophylaxis in predicted severe acute pancreatitis</td>
<td>Prof. H.G. Gooszen&lt;br&gt;Head, Department of Surgery&lt;br&gt;University Medical Center Utrecht, The Netherlands&lt;br&gt;Chairman Dutch Acute Pancreatitis Study Group</td>
<td>Investigator-initiated, multicenter, double-blind, placebo-controlled trial</td>
<td>Ongoing (start March 2004; estimated end 2007)</td>
<td>University Medical Center, Utrecht. Funded by Senter, an agency of the Ministry of Economic Affairs</td>
<td>Marc G.H. Besselink, MD&lt;br&gt;Utrecht, The Netherlands&lt;br&gt;Tel.: +31 30 250 8074&lt;br&gt;Fax: +31 30 254 1944&lt;br&gt;E-Mail: <a href="mailto:m.besselink@umcutrecht.nl">m.besselink@umcutrecht.nl</a></td>
</tr>
</tbody>
</table>

**Endpoint:** Total mortality and major morbidity

**Patient population:** Patients with (suspected) infected necrotizing pancreatitis, preferably >7 days after onset of symptoms

n=88
### Miscellaneous

**EUROPAC 2**  
Double-blind randomized controlled trial to investigate the efficacy of Antox and MGCT for the treatment of hereditary pancreatitis and idiopathic chronic pancreatitis  

- **Regimen:** Antioxidants for 1 year; Magnesium for 1 year  
- **Control:** Placebo  
- **Primary endpoint:** Reduction in the number of days of pancreatic pain  
- **Secondary endpoint:** Analgesic use; hospital admissions; quality of life scores  
- **Patient population:** Patients (5-65 years old) with hereditary pancreatitis or idiopathic chronic pancreatitis, registered with EUROPAC, having characteristic pain that is either intermittent or continuous  
- **Recruitment:** (start 2006)  
- **Contact:** Michael G.T. Raraty, MB, BS, PhD, FRCS  
  EUROPAC Study Coordinator  
  Liverpool, UK  
  Tel.: +44 151 706 4170  
  Fax: +44 151 706 5826  
  E-Mail: mraraty@liv.ac.uk / europac@liv.ac.uk

**POVATI:** Postsurgical pain outcome in patients with vertical and transverse abdominal incision: A randomized controlled equivalence trial  

- **Contact:** Prof. M.W. Büchler  
  Department of Surgery  
  University of Heidelberg  
  Germany  
  Tel.: +49 6221 56 6986  
  Fax: +49 6221 56 6988  
  E-Mail: christoph_seiler@med.uni-heidelberg.de  
  www.sdgc.de

**INSECT:** Interrupted or continuous slowly absorbable suture evaluation of abdominal closure techniques  

- **Contact:** Prof. M.W. Büchler  
  Department of Surgery  
  University of Heidelberg  
  Germany  
  Tel.: +49 6221 56 6986  
  Fax: +49 6221 56 6988  
  E-Mail: christoph_seiler@med.uni-heidelberg.de  
  www.sdgc.de
<table>
<thead>
<tr>
<th>Study</th>
<th>Description</th>
<th>Sponsor</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAPCON: Total laparoscopic versus conventional ileoanal pouch procedure: a randomized controlled trial</td>
<td>Prof. M.W. Büchler, Department of Surgery, University of Heidelberg, Germany</td>
<td>Ongoing</td>
<td>Prof. M.W. Büchler, Dr. Christoph Seiler, MSc, Heidelberg, Germany</td>
</tr>
<tr>
<td>CLIVIT: Clips vs. ligatures. A multicenter randomized controlled trial</td>
<td>Prof. M.W. Büchler, Department of Surgery, University of Heidelberg, Germany</td>
<td>Ongoing</td>
<td>BBD-Aesculap, Dr. Christoph Seiler, MSc, Heidelberg, Germany</td>
</tr>
<tr>
<td>Open, randomized, multicenter, phase IIIb study for 5 years to assess long-term efficiency and tolerability of esomeprazole compared to laparoscopic anti-reflux surgery in adult subjects with chronic gastroesophageal reflux disease</td>
<td>Lars Lundell, MD, Sahlgrenska University Hospital, Gothenburg, Sweden</td>
<td>Follow-up (end June 2013)</td>
<td>AstraZeneca, Dr. Christoph Seiler, MSc, Heidelberg, Germany</td>
</tr>
<tr>
<td>Mesh plug versus Lichtenstein, prospective and randomized study</td>
<td>Dr. A. Wildisen, Kantonales Spital Sursee-Wolhusen, Switzerland</td>
<td>Ongoing (end 2007)</td>
<td>Dr. A. Wildisen, Sursee-Wolhusen, Switzerland</td>
</tr>
<tr>
<td>Ongoing Clinical Trials (continued)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>A phase III, double-blind, randomized, parallel-group, placebo-controlled study of intravenous (IV) methylnaltrexone bromide (MNTX) in the treatment of post-operative ileus (POI)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Phase III, multicenter trial (75-90 centers worldwide)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Control:</strong> Placebo</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Regimen:</strong> IV MNTX 24 mg, MNTX 12 mg, or placebo for up to 10 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Endpoint:</strong> Length of time from end of surgery to first bowel movement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Patient Population:</strong> Patients scheduled for a segmental colectomy via open laparotomy with general anesthesia</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Ongoing**

**Progenics Pharmaceutical, Inc.**

Anna Williford, RN
Louisville, Ky., USA

Tel.: +1 502 583 0880
Fax: +1 502 585 2988
E-Mail: aowill01@gwise.louisville.edu
Questionnaire for Trial Submission

To submit information on a clinical trial for publication in the ‘Ongoing Clinical Trials’ section, please complete this short questionnaire.

1) Title of study (in full)


2) Lead investigator

Title:

Name:

Affiliation:

3) Field of study

Please indicate one or more of the following categories:

☐ Oncology    ☐ Inflammatory Bowel Disease
☐ Motility    ☐ Surgical Infection/Sepsis    ☐ Miscellaneous

Other (please specify):

4) Study phase (drug trials only)

Please indicate one of the following categories:

☐ Phase I    ☐ Phase II    ☐ Phase III    ☐ Phase IV
☐ Independent (investigator initiated)

5) Study design

☐ Multicenter    ☐ Single center (please indicate as appropriate)
If multicenter, please state how many centers are involved:

☐ Prospective    ☐ Retrospective (please indicate as appropriate)
If prospective, level of randomization (e.g. single blind, double blind, investigator-blind):

Controls (i.e. placebo-, active-, etc.):

Cross-over design (one-way, two-way, etc.):

Duration of therapy (if applicable):

Dosing regimen (if applicable):

Primary study endpoint:

Other information on study design (please include any other details that might be relevant):

6) Patients

Number of patients (planned):

Patient population (e.g. patients with mild UC previously controlled on…):

7) Current status of study

Start date:

Estimated end date:

Status (please indicate as appropriate):

☐ Development    ☐ Recruitment    ☐ Ongoing
☐ LPO    ☐ Analysis in progress

Publication

Abstract submitted to:

Manuscript submitted to:

8) Sponsor

9) Contact for further information:

Name:

Address:

Telephone:

Fax:

E-Mail:

Please return the completed questionnaire as soon as possible to the Section Editor:

Susan Galandiuk, MD
Department of Surgery
School of Medicine
University of Louisville
Louisville, KY 40292, USA
Tel.: +1 502 852 5442
Fax: +1 502 852 8915

or contact:

S. Karger AG
Attn.: Ms. Yvonne Rebmann
Allschwilerstrasse 10
PO Box
CH–4009 Basel
Tel.: +41 61 306 13 51
Fax: +41 61 306 12 34
E-Mail: y.rebmann@karger.ch