Overview of trials running in the Benelux

(Belg J Med Oncol 2012;6:26-36)

The PASCE trial

cutaneous squamous cell carcinoma - phase II - EGFR - antibody - overall response rate

The PASCE trial is an open label multicentre phase II study of panitumumab in cutaneous squamous cell carcinoma (SCC). This study will evaluate the efficacy of panitumumab, an antibody against epidermal growth factor receptor (EGFR) in patients with a cutaneous SCC.
Activation of *EGFR* and *RAS* signalling pathways has been reported to play an important role in disease progression, possibly through downregulation of the immune system. Therefore, the study comprises a translational component (blood sample, tumour- and skin biopsies) for analysing the modification of some *EGFR* signalling pathway key protein expression profiles and in the regulation of the immune system.
The primary aim consists of measuring the efficacy of panitumumab for SCC in terms of overall response rate. Secondary objectives include the safety profile, the time to treatment failure, the time to treatment progression and duration of response.

For more information, please contact:
Jean-François Baurain, MD, PhD
E-mail: jean-francois.baurain@uclouvain.be

Phase I/II study of peptide vaccination associated with tumour immunomodulation with pro-inflammatory cytokines and imiquimod in patients with advanced metastatic melanoma

metastatic melanoma - phase I/II - vaccination - cytokines - tumour response rate

The study will determine whether peptide vaccination associated with local peritumour treatment with a combination of interleukin-2, interferon-alpha, granulocyte-macrophage colony stimulating factors, and imiquimod, induces tumour responses. Patients with regional disease or with distant metastatic disease, and with at least 2 cutaneous metastases will be included. Moreover, the tumour of the patient should express either the antigen MAGE3-A1 or NA17.A2.
The tumour response will be reported according to the RECIST 1.1 guideline. We will also document the toxicity of treatment, and induction of T lymphocyte responses to the vaccine.

For more information, please contact:
Jean-François Baurain, MD, PhD
E-mail: jean-francois.baurain@uclouvain.be

Phase I/II study of therapeutic vaccination with escalating doses of CyaA-Tyr, a proteinic vector targeting dendritic cells, coupled to a melanoma antigen, in patients with advanced metastatic melanoma

metastatic melanoma - phase I/II - vaccination - proteinic vector - tyrosinase

This **phase I/II** study will test doses of a novel vaccine CyaA-Tyr in patients with advanced metastatic melanoma. Patients with ocular, mucosal or cutaneous melanoma will be included.
Previous tests on mice demonstrated that this vaccine CyaA-Tyr can induce strong and longlasting tyrosinase specific CTL responses. The safety and the toxicity of increasing doses of CyaA-Tyr will be monitored, as well as induction of immune response and clinical response.

For more information, please contact:
Jean-François Baurain, MD, PhD
E-mail: jean-francois.baurain@uclouvain.be

A dosimetric study comparing breast radiotherapy planned in prone versus supine position and via conformal 3D versus IMRT techniques: protocol B-POS

breast - dosimetry - gating - IMRT - prone - radiotherapy - supine

Breast cancer is the most frequently diagnosed cancer in women. Radiotherapy is an essential component of the curative treatment algorithm. The current standard of care is radiotherapy, in the supine position, to the whole breast by 3D conformal planning. However, several questions remain regarding dose delivery and technique optimization. Can patient positioning improve dose homogeneity? Can the prone position reduce error associated with patient breathing or decrease the dose to healthy organs and tissues? This study is designed to compare prone versus (conventional) supine treatment and the impact of respiratory motion in each position. The benefits of IMRT versus conventional 3D conformal planning (in each position) will be compared with regard to dose delivery to the breast, dose to healthy organs and tissues and cost-efficiency regarding departmental resources. The results of this study will serve for the standardization of breast radiotherapy techniques within the Liège University Hospital.

For more information please contact:
Philippe Coucke
E-mail: pcoucke@chu.ulg.ac.be

SORCE trial: a phase III randomised double-blind study comparing sorafenib to placebo in patients with resected primary renal cell carcinoma at high or intermediate risk of relapse

accrual ongoing - phase III - renal cell carcinoma - sorafenib

This **multicentre phase III trial** aims to assess the efficacy and tolerability of sorafenib in patients with resected renal cell carcinoma (RCC). Patients will be randomised to 3 treatment arms: 3 years placebo, 1 year sorafenib + 2 years placebo, or 3 years sorafenib. The main endpoints of the study are disease-free survival, RCC-specific survival, overall survival, and toxicity.

For more information please contact:
Steven Joniau, study coordinator for Belgium
E-mail: steven.joniau@uz.kuleuven.ac.be

EORTC 22043-30041 trial: postoperative external radiotherapy combined with concomitant and adjuvant hormonal treatment versus postoperative external radiotherapy alone in pathological stage pT3a-b R0-1 N0M0, Gleason score 5-10 prostate carcinoma

accrual start: May-June 2009 - hormonotherapy - phase III - prostate cancer - radiotherapy

This **multicentre phase III trial** aims to investigate the potential benefit of a combined adjuvant treatment (short-term androgen suppression and postoperative radiotherapy) for improving the biochemical progression-free survival of patients who have undergone radical prostatectomy for cT1-2-3a N0M0 prostate cancer with baseline prostate-specific antigen (PSA) level ≤5x upper limit of normal range, and who present postoperatively with pathologic stage pT2 R1 / pT3-b R0-1 N0M0, Gleason score 5-10, and an undetectable postoperative PSA level.
Patients will be randomised between postoperative irradiation alone or postoperative irradiation and short-term adjuvant androgen deprivation.
The main endpoints of the study are biochemical and clinical progression-free survival, distant metastasis-free survival, overall survival, and toxicity.

For more information please contact:
Hendrik Van Poppel, Michel Bolla, study coordinators
E-mail: mbolla@chu-grenoble.fr;
hendrik.vanpoppel@uz.kuleuven.ac.be

Assessing the efficacy of the combination of gemcitabine and cetuximab (ECHO) in advanced cholangiocarcinoma

BGDO - cetuximab - cholangiocarcinoma - gemcitabine - phase II

The Belgian Group of Digestive Oncology (BGDO) is launching a **phase II trial** assessing the efficacy of the combination of gemcitabine and cetuximab in advanced cholangiocarcinoma: the **ECHO trial**. These rare tumours represent an orphan disease, with no standard treatment and only phase II trials in the literature. If efficacy is shown after the first 13 patients, this study will hopefully include 45 patients. The aim of the study is to assess progression-free survival at 6 months, hoping to improve it from 20% (as estimated from the trials using gemcitabine) to 40% with the combined regimen. As biliary tract tumours express K-RAS in 50% of the cases, translational research will also be performed to see if mutated K-RAS can be predictive of response.

For more information please contact:
Ivan Borbath, Jean-Luc Van Laethem, study coordinators
E-mail: ivan.borbath@uclouvain.be, jvlaethe@ulb.ac.be

Activity of sunitinib in oesophageal cancer, melanoma and sarcoma (SEMS)

melanoma - oesophageal cancer - phase II - sarcoma - sunitinib

The melanoma and sarcoma cancer cohorts have been completed. Accrual continues in oesophageal cancer. Therapeutic options in patients with advanced oesophageal cancer, melanoma and sarcoma are limited after failure of standard first-line chemotherapy. In the present, **multicentre 2-stage phase II trial** the activity of the single agent sunitinib malate (Sutent®) administered orally at 50 mg/day, 4 weeks on followed by 2 weeks off, will be examined.

Inclusion criteria:

- advanced cancer, locally or metastatic;
- presence of plasma and tissue sample;
- life expectancy of >3 months;
- measurable disease or disease evaluable with non-measurable laesions or tumour marker;
- disease progression on prior treatment and anti-cancer therapy-free period of >4 weeks before baseline examination for current study;
- Tumour-specific inclusion criteria:
  - **sarcoma and melanoma cohorts are closed (recruitment completed)**;
  - **oesophageal cancer**: second line after cisplatinum based chemotherapy.

The study comprises a translational component including

- baseline plasma levels of VEGF-A, sVEGFR-2, sVEGFR-3 and placenta growth factor (PlGF);
- tumour gene copy number of VEGFR-2;
- evolution during treatment of circulating endothelial and tumour cells. Perfusion imaging with dynamic contrast enhanced MRI.

For more information please contact:
Ellen Dewandeler, datamanager;
Lore Decoster, Jacques De Grève, PI's
E-mail: ellen.dewandeler@uzbrussel.be

The SOLE trial

disease free survival - early stage breast cancer - endocrine therapy - letrozole - phase III trial

The SOLE trial is a phase III trial evaluating the role of continuous letrozole versus intermittent letrozole following 4 to 6 years of prior adjuvant endocrine therapy in postmenopausal women with hormone receptor-positive, node-positive, early stage breast cancer (SOLE / IBCSG 35-07 / BIG 1-07).

For more information please contact:
Guy Jerusalem, study coordinator for Belgium
E-mail: g.jerusalem@chu.ulg.ac.be

Open label phase Ia/Ib study of two dosing schedules of BI 847325, orally administered once a day in patients with advanced solid tumours, with repeated cyclic administration in patients with clinical benefit

MEK inhibitor – Phase Ia/Ib – solid tumours

BI 847325 is an orally available dual inhibitor of MEK and aurora kinase. In this ongoing dose escalation phase

Ia/Ib study, BI 847325 is investigated as monotherapy in patients with advanced/metastatic solid tumours. The aim of the ongoing phase Ia (dose escalation) part of this study is to assess the maximum tolerated dose and safety of BI 847325 administered at escalating doses in 2 treatment arms using different schedules. In the phase Ib expansion part of the trial, that will start soon, the aim is to further evaluate the safety profile of BI 847325 at the recommended dose and schedule and to assess target modulation and the potential anti-tumour efficacy in patients with selected tumour types.

The main inclusion criteria are: Patients with a histologically or cytologically confirmed diagnosis of an advanced unresectable and/or metastatic solid tumour, and who have failed conventional treatment or for whom no therapy of proven efficacy exists or who are not amenable to standard therapies, age 18 years and older, written informed consent consistent with ICH-GCP and local legislation, ECOG 0 or 1, recovery of therapy-related toxicities from previous anti-tumour therapies to CTCAE grade 1 (with the exception of alopecia), written informed consent to the use of archival tumour sample for determination of the BRAF/RAS mutational status and a life expectancy of at least 12 weeks. In addition, all patients included in the expansion cohort phase (part Ib) must have been diagnosed with one of the following tumours: melanoma, colorectal carcinoma, non small cell lung cancer (NSCLC) or exocrine pancreas adenocarcinoma, and have been shown on their archival tumour sample to have KRAS or BRAF mutation. Furthermore they should have measurable disease, documented/proven progressive disease within the last 6 months, according to Response Evaluation Criteria In Solid Tumors (RECIST) criteria and a tumour laesion accessible for biopsies (pre- and post-treatment): this is mandatory for patients with colorectal carcinoma or melanoma, optional for patients with NSCLC or exocrine pancreas adenocarcinoma.

Main exclusion criteria are inability to swallow tablets, additional other serious illness, concomitant non-oncological disease (e.g. active infectious disease or known chronic Hepatitis B/Hepatitis C infection and HIV), or ongoing toxicity from prior therapies considered by the investigator to potentially compromise patient's safety in this trial, clinical evidence of symptomatic progressive brain or leptomeningeal disease during the last 28 days, second malignancy currently requiring another anti-cancer therapy, absolute neutrophil count less than 1,500/mm^3, platelet count less than 100,000/mm^3, bilirubin greater than 1.5 mg/dL (>26 μmol/L, SI unit equivalent) (except known Gilbert's syndrome), aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT) greater than 2.5 times the upper limit of normal (if related to liver metastases, greater than five times the upper limit of normal), serum creatinine greater than 1.5 mg/dL (>132 μmol/L, SI unit equivalent), previous episode of QT prolongation due to a medication which, as a result of it, had to be discontinued; or long QT syndrome; or QTc with Fridericia's correction >480 msec on screening ECG, treatment with other investigational drugs or participation in another clinical interventional trial within the past four weeks before start of therapy or concomitant with this trial, and systemic anti-cancer therapy or radiotherapy within the past four weeks before start of therapy or concomitantly with this trial. This restriction does not apply to LHRH agonists, steroids and bisphosphonates.

For more information please contact:
Patrick Schöffski, MD, PhD
E-mail: patrick.schoffski@uz.kuleuven

LAPATAX: A phase I-II study of Lapatinib and Docetaxel as neoadjuvant treatment for locally advanced breast cancer.

lapatinib - breast cancer - neoadjuvant chemotherapy

The refinement of targeted therapy against HER2 is being assessed in the EORTC 10054 trial (Lapatax). This is a randomized phase II trial of FEC-Docetaxel combined with Lapatinib and/or Trastuzumab as neoadjuvant therapy of HER2-positive operable breast cancer. The trial, which plans to include 150 patients, is currently open for accruals in various European centers. Lapatax is also collecting frozen tumor and blood samples for translational research. The goal of the trial Is to compare the pathological complete response rate between the treatment arms.

For more information please contact:
Gustavo Werutsky (CRP)
E-mail: Gustavo.werutsky@eortc.be

Male BC: Clinical and biological characterization of Male Breast Cancer: an international retrospective EORTC, BIG and NABCG intergroup study.

breast cancer - male breast cancer

The clinical and biological characterization of male BC is the subject of EORTC 10085 BIG2-07 trial. This is an international joint effort between Breast International Group (BIG), North American Breast Cancer Group (NABCG) and the European Organisation for Research and Treatment of Cancer (EORTC) which is the study legal sponsor and coordinator. Centers affiliated to these groups will collect about 1600 patient data and biological material for several biomarker analyses and biobanking. These results will enable us to decide if a clinical trial for this rare disease could be launched in the future. The goal of the trial is to make retrospective analysis of clinical and biological data of male breast cancer (BC) patients treated in the last 20 years .

For more information please contact:
Gustavo Werutsky (CRP)
E-mail: Gustavo.werutsky@eortc.be

EORTC 55994: Randomized phase III study of neoadjuvant chemotherapy followed by surgery vs. concomitant radiotherapy and chemotherapy in FIGO Ib2, IIa > 4 cm or IIb cervical cancer.

cervical cancer – EORTC - neoadjuvant

The objective of the study is to demonstrate a survival advantage with the use of neoadjuvant chemotherapy followed by radical surgery compared to a standard approach consisting of concomitant chemotherapy and radiotherapy in FIGO stage Ib2, IIa> 4 cm, IIb cervical cancer.

For more information please contact:
Björn Penninckx (CRP)
E-mail:bjorn.penninckx@eortc.be

EORTC 06031: Gemtuzumab Ozogamicin (GO) monotherapy versus standard supportive care for previously untreated AML in elderly patients who are not eligible for intensive chemotherapy: a randomized phase II/III trial (AML-19) of the EORTC-LG and GIMEMA-ALWP.

gemtuzumab – AML - elderly

The aim of this sequential phase II-III trial is to compare 2 strategies of treatment for elderly patients with previously untreated AML, who are not eligible for intensive chemotherapy. We will test standard supportive care versus gemtuzumab monotherapy for induction/continuation. In phase II, we will assess the feasibility, toxicity profile and antileukemic activity of two different regimens of Gemtuzumab Ozogamicin (GO) monotherapy as induction treatment in the study population. In phase III, we will prospectively compare efficacy and toxicity of GO monotherapy versus standard supportive care. The main endpoint will be the duration of survival.

For more information please contact:
Matthias Karrasch (CRP)
E-mail: matthias.karrasch@eortc.be

EORTC 06061: Clofarabine in combination with a standard remission induction regimen (AraC and idarubicin) in patients 18-60 years old with previously untreated intermediate and bad risk acute myelogenous leukemia (AML) or high risk myelodysplasia (MDS): a phase I-II study of the EORTC-LG and GIMEMA (AML-14A trial)

AML – MDS - clofarabine

This is an open label, 2-arm multicenter trial with a sequential phase I-II design. The main of objective of the phase I part is to determine the optimum dose of Clofarabine (1-hour i.v. or push injection over 10 minutes) in combination with cytosine arabinoside and idarubicine to be recommended for the phase II

trial. The main objective of the randomized phase II part of the trial is to explore the antitumor activity of the above mentioned treatment combination using the recommended dose of Clofarabine (1-hour i.v. or push injection over 10 minutes) as defined in the phase I.

For more information please contact:
Matthias Karrasch (CRP)
E-mail: matthias.karrasch@eortc.be

EORTC 58051: Interfant 06 - international collaborative treatment protocol for infants under one year with acute lymphoblastic leukaemia.

infants under 1 year - ALL

The primary aim of this study is to assess the role of an early intensification of two "AML" induction blocks versus protocol Ib directly after induction. Secondary aims are to assess the overall outcome of the Interfant-06 protocol compared to the historical control series, especially the Interfant-99, to study which factors have independent prognostic value and to assess the role of SCT in HR patients and MR patients with MRD levels of ≥ 10e-4 at the start of OCTADA(D).

For more information please contact:
Matthias Karrasch (CRP)
E-mail: matthias.karrasch@eortc.be

EORTC 58081: observational study for identification of new possible prognostic factors and future therapeutic targets in children with acute lymphoblastic leukaemia (ALL)

children - ALL

Biobanked material will be partly used to perform specific translational projects as defined in the present protocol, to identify new prognostic factors (e.g. MRD significance in small subgroups, miRNAs expression profile, PAX5 mutation, genetic abnormalities in T-ALL, RAS pathway activation), identify leukaemia cell genetic alterations (e.g. mutations in T-ALL, miRNA expression in B-ALL) and related molecular pathways (e.g. RAS pathway) underlying leukemogenesis. And to identify patient pharmacogenetic polymorphisms impacting individual response to corticosteroids as part of standard therapy and investigate their prognostic significance. Remaining material will be stored for possible future research projects as new research questions and research methods may come up in the future.

For more information please contact:
Matthias Karrasch (CRP)
E-mail: matthias.karrasch@eortc.be

EORTC 58LE : Assessment of the long term outcome of childhood ALL patients enrolled in EORTC CLG trials between 1971 and 1998.

children - ALL

The aim of this retrospective project is to assess the long term outcome of childhood ALL patients enrolled in EORTC CLG trials between 1971 and 1998, and in particular to assess the long term survival, the long term disease status, the occurrence of late adverse effects, the occurrence of second cancers and the socioeconomic status of the survivors.

For more information please contact:
Matthias Karrasch (CRP)
E-mail: matthias.karrasch@eortc.be

EORTC 26053-22054 : Phase III trial on concurrent and adjuvant temozolomide chemotherapy in non-1p/19q deleted anaplastic glioma. The CATNON intergroup trial.

temozolomide - anaplastic glioma

This study is conducted jointly by the EORTC Brain Tumor and Radiation Oncology Groups is performed in cooperation with North America through the RTOG. Contribution to the trials is also ensured through the participation of Australia and national European groups such as MRC in the United Kingdom. It will establish

whether concurrent and adjuvant temozolomide improves the outcome of patients with non-codeleted 1p/19q anaplastic gliomas. Patients will be randomized in a 2 x 2 design to radiotherapy (with further treatment including chemotherapy if indicated at the time of progression), radiotherapy with concurrent temozolomide, radiotherapy followed by adjuvant temozolomide and radiotherapy with concurrent temozolomide followed by adjuvant temozolomide. The trial is actively recruiting.

For more information please contact:
Denis Lacombe (CRP)
E-mail: denis.lacombe@eortc.be

EORTC 26081-22086 : Phase III Intergroup Study of Radiotherapy versus Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with Newly Diagnosed Anaplastic Oligodendroglioma or Anaplastic Mixed Glioma with Chromosomal Co-delections of 1p and 19q.

temozolomide - anaplastic oligodendroglioma - anaplastic mixed glioma

This is a study initiated by the US NCCTG and is Phase III Intergroup Study of Radiotherapy versus Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with 1p/19q Codeleted Anaplastic Glioma. It is the complemetatry study to EORTC 26053-22054 as grade III gliomas may be directed to either protocol depending on their tumor 1p/19q status. The study is aimed at determining whether there is a survival advantage for those who receive concomitant temozolomide and RT followed by adjuvant temozolomide over that observed in patients treated with RT alone for which is principally powered. The study is currently recruiting in Europe through the EORTC brain tumor and radiation Oncology group.

For more information please contact:
Denis Lacombe (CRP)
E-mail: denis.lacombe@eortc.be

EORTC 26062-22061 : A randomized phase III study of Temozolomide and short-course radiation versus short-course radiation alone in the treatment of newly diagnosed glioblastoma multiforme in elderly patients.

temozolomide - glioblastoma

This a randomised phase III study of Temozolomide and short-course radiation versus short-course radiation alone in the treatment of newly diagnosed glioblastoma multiforme in elderly patients In view of the phase III results which showed an advantage in combining temozolomide with RT in GBM, but leaves doubts as to whether this advantage extends to an elderly patient population. In addition, given recent results demonstrating no differences in survival in elderly GBM patients treated with a 40 Gy/15 versus a 60 Gy/30 dose of RT, and the lower tolerance of this patient population to RT, the 40 Gy/15 (short-course) dose will be employed in this trial. This trial is initiated by the NCI-Canada trials groups and European recruitment is ensured by both the EORTC Brain Tumor and Radiation Oncology groups.

For more information please contact:
Denis Lacombe (CRP)
E-mail: denis.lacombe@eortc.be

EORTC 26082-22081 : Radiation therapy and concurrent plus adjuvant Temsirolimus (CCI-779) versus chemo-irradiation with temozolomide in newly diagnosed glioblastoma without methylation of the MGMT gene promoter - a randomized multicenter, open-label, Phase II study.

Temsirolimus – temozolomid - glioblastoma

This is a randomised phase II addressing radiation therapy and concurrent plus adjuvant Temsirolimus (CCI-779) versus chemo-irradiation with temozolomide in newly diagnosed glioblastoma without methylation of the MGMT gene promoter. The rationale for

this trial is based on the fact that patients with high grade glioma containing a hypermethylated MGMT promoter benefited from TMZ (overall survival rate at 24 months: 46% vs. 23%), whereas those who did not have a methylated MGMT promoter did have a significantly worse survival and less benefit from the addition of TMZ to RT (OS rate at 24 months: 14% vs. < 2%). This is a randomized controlled phase II study with 12 months OS as the primary endpoint. Tumors will be molecularly characterized by the methylation status of the MGMT gene promoter gene.

For more information please contact:
Denis Lacombe (CRP)
E-mail: denis.lacombe@eortc.be

EORTC 26091: Randomized trial assessing the significance of Bevacizumab in recurrent grade II and Grade III gliomas. The TAVAREC trial.

Bevacizumab - glioma

This is a randomised trial of the Brain Tumor Group assessing the significance of Bevacizumab in recurrent grade II and grade III gliomas. This study will therefore investigate if there is any evidence that the addition of bevacizumab to temozolomide improves outcome in recurrent grade II and grade III tumors documented by the probability of survival at one year. The study is currently recruiting. In addition to a solid translational research agenda, this trial offers the possibility to assess in a prospective fashion the new criteria for assessing treatment activity in neuro-oncology through a centralized imaging program.

For more information please contact:
Denis Lacombe (CRP)
E-mail: denis.lacombe@eortc.be

EORTC 26101: Phase II trial exploring the sequence of bevacizumab and lomustine in patients with first recurrence of a glioblastoma.

bevacizumab - glioblastoma

Goal of the study: this is a phase II trial of the Brain Tumor Group exploring the sequence of bevacizumab and lomustine in patients with first recurrence of a glioblastoma. The role of bevacizumab in glioblastoma is unclear and specially the appropriate time to use it during the evolution of the disease. Because of the substantial neovascularization seen in glioblastoma, targeted therapies with antiangiogenic activity may have a role in glioma therapy. The treatment arms address the sequence of both agents as it will allow randomization between the combination of the 2 agents vs lomustine at start followed by bevacizumab at progression vs bevacizumab at start and further combined with lonustibe at progression. Lomustinbe single arm will serve as reference arm.

For more information please contact:
Denis Lacombe (CRP)
E-mail: denis.lacombe@eortc.be

EORTC 30061: Phase I study of cisplatin, gemcitabine and lapatinib as first line treatment in advanced/metastatic urothelial cancer.

phase I – lapatinib - transitional cell carcinoma

A phase I, multinational, open-label, dose-escalation study of lapatinib in combination with gemcitabine and cisplatin in patients with advanced or metastatic urothelial cancer. Patients will be allocated to dose levels according to the scheme 3+3. The dose escalation is based on the acute toxicity observed in patients and only the dose of lapatinib is escalated. The principal objective of the trial is to assess the safety profile of the standard treatment gemcitabine and cisplatin in combination with lapatinib in order to determine the recommended dose for phase II.

For more information please contact:
Sandrine Marreaud (CRP)
E-mail: sandrine.marreaud@eortc.be

EORTC 30073: Randomized phase III trial comparing immediate versus deferred nephrectomy in patients with synchronous metastatic renal cell carcinoma.

phase III – nephrectomy - metastatic renal cell carcinoma

Surtime is a multi-centre, open label, randomised phase III study investigating the best sequence for surgery in patients with metastatic renal cell cancer (mRCC) having a resectable asymptomatic in situ primary. Patients are randomly assigned to immediate versus deferred nephrectomy. In the immediate nephrectomy arm patients will receive sunitinib after surgery and in the deferred nephrectomy arm they will receive sunitinib before (3 cycles) and after surgery. The principal objective of the trial is to investigate whether deferring nephrectomy in patients who receive sunitinib has an effect on disease control by optimising the sequence of surgery for mRCC.

For more information please contact:
Sandrine Marreaud (CRP)
E-mail: sandrine.marreaud@eortc.be

Medical Research Council RE05/EORTC protocol 30072: A phase III randomised double-blind study comparing sorafenib with placebo in patients with resected primary renal cell carcinoma at high or intermediate risk of relapse.

phase III – sorafenib - renal cell carcinoma

SORCE is a multi-centre randomised phase III double-blind placebo-controlled study examining the efficacy and tolerability of sorafenib (Nexavar) in patients with resected (total or partial) primary renal cell carcinoma at high or intermediate risk or relapse. Patients are randomly assigned to 3 years of placebo or 1 year sorafenib followed by 2 years placebo or 3 years sorafenib. SORCE aims to answer two questions. The first question is whether at least one year of treatment with sorafenib increases disease-free survival (DFS) compared with placebo. The second question is about the duration of sorafenib and whether three years of treatment increases DFS compared to one year.

For more information please contact:
Sandrine Marreaud (CRP)
E-mail: sandrine.marreaud@eortc.be

22042- 26042: Adjuvant post-operative high-dose radiotherapy for atypical and malignant meningioma : a Phase II and observation study

meningeoma – radiotherapy - postoperative

The objectives of this EORTC phase II study is to assess the impact of high-dose radiotherapy on progression-free survival, treatment tolerance, and post-treatment global cognitive functioning in patients with operated either atypical (Grade WHO II, phase II) or malignant (grade WHO III, registration study) meningeoma. The accrual is driven by the Phase II study, in which a total of 54 patients with atypical meningeoma is to be included. The radiotherapy dose with Simpson stage 1-3 is 60Gy and with stage 4-5 up to 70Gy. The primary endpoint is the progression-free survival rate at 3 years in the phase II study.

For more information please contact :
Liisa Pylkkanen (CRP)
E-mail : liisa.pylkkanen@eortc.be

22051-10052: Selective Use of Postoperative Radiotherapy AftEr MastectOmy (SUPREMO)

breast cancer - radiotherapy- postoperative

The objective of this randomised Phase III intergroup (EORTC, MRC, BIG) study is to determine the effects of ipsilateral chest wall irradiation following mastectomy and axillary surgical staging for women with operable breast cancer at intermediate risk of locoregional recurrence. The patients will be randomized either to receive postoperative radiotherapy (the total radiotherapy dose is 40 – 50 Gy depending fractionation regimen) or in the follow-up arm. Up to 1600 patients is to be included in the study. The primary endpoint is overall survival, and secondary endpoints

include e.g., chest wall and regional recurrence, disease-free survival, quality of life and cost-effectiveness.

For more information please contact :
Liisa Pylkkanen (CRP)
E-mail : liisa.pylkkanen@eortc.be

22085-10083: A randomised phase III study of radiation doses and fractionation schedules for ductal carcinoma in situ (DCIS) of the breast.

breast cancer - ductal carcinoma in situ (DCIS) - radiotherapy - postoperative

The overall objectives of this randomized phase III intergroup (EORTC, TROG, BIG) study are to improve the outcome of women with non-low risk ductal carcinoma in situ (DCIS) treated with breast conserving therapy and to individualize treatment selection for women with DCIS to achieve long term disease control with minimal toxicity. Up to 1600 patients with completely excised non-low risk DCIS will be included in the study. The primary endpoint is the time to local recurrence, and the secondary endpoints are overall survival, time to disease recurrence, cosmetic outcome, radiation toxicity and quality of life.

For more information please contact :
Liisa Pylkkanen (CRP)
E-mail : liisa.pylkkanen@eortc.be

Ongoing and expected trials in oncology at the Antwerp University Hospital (UZA)

- A prospective, randomised study comparing the 70-gene signature with the common clinical-pathological criteria in selecting patients for adjuvant chemotherapy in breast cancer with 0-3 positive nodes (MINDACT).
  Setting: breast cancer, adjuvant therapy
  Status: ongoing
  For more information please contact Joke Dyck, e-mail: joke.dyck@uza.be

- A multicentre, open-label, phase II study to evaluate the safety of NKTR-102 (PEG-irinotecan) when given on a q14 day or q21 day schedule in patients with metastatic or locally advanced breast cancer whose disease has failed prior taxane-based treatment.
  Setting: breast cancer, second- and third-line treatment
  Status: ongoing
  For more information please contact Joke Dyck, e-mail: joke.dyck@uza.be

- A randomised phase III trial of neoadjuvant chemotherapy followed by surgery versus concomitant radiotherapy and chemotherapy in FIGO Ib2, Iia, >4 cm or IIb cervical cancer (EORTC 55994).
  Setting: gynecological cancer, preoperative
  Status: ongoing
  For more information please contact Joke Dyck, email: joke.dyck@uza.be

- Preoperative chemosensitivity testing as predictor of treatment benefit in adjuvant stage III colon cancer (PePiTA trial).
  Setting: colon cancer, adjuvant setting
  Status: ongoing
  For more information please contact Peggy De Clercq, e-mail: peggy.de.clercq@uza.be

- An open-label, randomised phase III study on the efficacy and tolerability of linifanib (ABT-869) versus sorafenib in subjects with advanced hepatocellular carcinoma (protoc M10-963).
  Setting: hepatocellular cancer, first-line treatment
  Status: ongoing
  For more information please contact Véronique Derwael,
  e-mail: véronique.derwael@uza.be

- Intravenous versus intra-arterial fotemustine chemotherapy in patients with liver metastases from uveal melanoma: a randomised phase III study (EORTC 18021).
  Setting: melanoma, second-line treatment
  Status: ongoing
  For more information please contact Joke Dyck, e-mail: joke.dyck@uza.be

- Study of bevacizumab, temozolomide, and radiotherapy in patients with newly diagnosed glioblastoma (AVAGLIO).

Setting: glioblastoma, first-line treatment
Status: ongoing
For more information please contact Ingrid Aelbrecht,
e-mail: ingrid.aelbrecht@uza.be

- A randomised trial of single agent doxorubicin versus doxorubicin plus ifosfamide in the first-line treatment of advanced or metastatic soft tissue sarcoma (EORTC 62012).
  Setting: soft tissue sarcoma, first-line treatment
  Status: ongoing
  For more information please contact Joke Dyck,
  e-mail: joke.dyck@uza.be

- A randomised phase II feasibility study of cetuximab combined with 4 cycles of docetaxel, cisplatin, and 5-FU (TPF) followed by platinum-based chemoradiation strategies (EORTC 24061).
  Setting: head and neck cancer, first-line treatment
  Status: on hold
  For more information please contact Ingrid Aelbrecht,
  e-mail: ingrid.aelbrecht@uza.be

- Phase II study of pemetrexed in combination with cisplatin and cetuximab in recurrent and metastatic squamous cell carcinoma of the head and neck (Eli Lilly).
  Setting: head and neck cancer, recurrent and metastatic
  Status: ongoing
  For more information please contact Ingrid Aelbrecht,
  e-mail: ingrid.aelbrecht@uza.be

- A phase I/II open-label study of bosutinib (SKI-606) administered in combination with capecitabine in subjects with solid tumour (colorectal, pancreatic, cholangio, glioblastoma) andErbB2-negative locally advanced or metastatic breast cancer.
  Setting: phase I
  Status: ongoing
  For more information please contact Joke Dyck,
  e-mail: joke.dyck@uza.be

- A single-arm, open-label phase II study: treatment beyond progression by adding bevacizumab to capecitabine plus oxaiplatin (XELOX) chemotherapy in patients with metastatic colorectal cancer and disease progression under first-line leucovorin, 5-FU, and irinotecan (FOLFIRI) + bevacizumab combination (AVASTAY).
  Setting: colorectal cancer, second-line treatment
  Status: expected
  For more information please contact Peggy De Clercq,
  e-mail: peggy.de.clercq@uza.be

- A phase II, open-label study to assess the efficacy and safety of lenalidomide in combination with cetuximab in pretreated subjects with KRAS mutant metastatic colorectal cancer (Celgene).
  Setting: colorectal cancer, third-line treatment
  Status: expected
  For more information please contact Peggy De Clercq,
  e-mail: peggy.de.clercq@uza.be

- Asymptomatic colon cancer with synchronous resectable liver metastases: a pilot phase II multicentre study.
  Setting: colon cancer
  Status: expected
  For more information please contact Peggy De Clercq,
  e-mail: peggy.de.clercq@uza.be

- Evaluation of preoperative induction chemotherapy and chemoradiation using cisplatin, infusional 5-FU and panitumumab in locally advanced oesogastric adenocarcinomas: a phase IIa study.
  Setting: gastric cancer, neoadjuvant treatment
  Status: ongoing
  For more information please contact Peggy De Clercq,
  e-mail: peggy.de.clercq@uza.be

Institutional websites with information on recruiting trials

Medische Oncologie UZ Leuven
http://www.uzleuven.be/nl/ig-algemeen-medische-oncologie/klinische-studies
Medische Oncologie UZ Brussel
http://www.uzbrussel.be/u/view/nl/2555295-Medische+oncologie.html
Password needed for access to in/exclusion criteria can be requested at
datamanagement.oncologischcentrum@uzbrussel.be