

Up to October, 1988, 245 patients are registered. External review is started. 350 patients are required in this trial to reach 200 randomized cases.

Protocol 10861 : randomized phase II study : second line endocrine treatment of postmenopausal patients with advanced breast cancer. A total of 148 patients entered the study so far. 215 evaluable cases are required to complete this study. Half of the cases entered were reviewed in the Data Center. The decision on closing 1 arm of the trial will be done by the study coordinators together with the statistician.

Protocol 10881 : randomized phase III trial for premenopausal advanced breast cancer patients randomized to receive either LHRH-agonist, or LHRH-agonist + tamoxifen or tamoxifen alone. For practical reasons, the trial was activated very recently and so far 9 patients have been randomized. A large number of new centers are interested in this study.

Protocol 10871 : a randomized phase II trial of doxorubicin in different dosages and schedules for advanced breast cancer, used as second line in CMF refractory patients. The study accrued to 32 patients. Although the accrual is far under the expected number, the study coordinator prefers to continue for another 6 months and meanwhile to investigate the possibilities for continuing the study.

Prevalence of endometrial cancer in Nolvadex treated patients (W. Mattheiem)
The organization of a prospective randomized study is discussed. The Peto group will be asked to include the problem in their overview analysis of adjuvant therapy studies.

Next meetings
Barcelona, May 11-12, 1989
Leiden, November 9-10, 1989

List of commitments - London Meeting 11/88

Ongoing protocols :

I. Fentiman : 10853 DCIS : form discussion 10850-10851 : Elderly : modify inclusion criteria -> PRC -> approval sent to members

F. Zoetmulder : 10873 Paget : forms to be finalized

M. Nooij : 10871 Adria : investigate feasibility

P. Bruning, C. Rose, H. Mouridsen, R. Sylvester : decision on closing 1 arm of the study

New projects :

P. Bruning and L. Beex : final proposal(s) diphosphonate study

A.N. Van Geel : treatment policy local recurrence

General proposals :

Quality control in surgery : J.A. van Dongen, C. van de Velde, W. Mattheiem, F. Zoetmulder

Phase II Working Group : structure : M. Piccart, P. Bruning, M. Nooy, E. van der Schueren

Dominant Site of Disease Working Party : elaboration of standard guidelines : K. Vantongelen, H. Stewart, E. Engelsman, L. Beex, J. Wildiers

Letter to Peto Group -> prevalence of endometrial cancer in tamoxifen treated patients. J.A. van Dongen

Publications :

H. Mouridsen : 10811, cardiotoxicity data

C. Rose : 10802 MPA trial data

E. Engelsman : 10808 CMF classical vs IV

R. Paridaens : 10761 Levamisole

H. Mouridsen, C. Rose : 10834 : second line endocrine

J.A. van Dongen : 10801 breast conservative treatment

REPORT EORTC LUNG COOPERATIVE GROUP MEETING
Interlaken, August 31, 1988

Business meeting

As an introduction, new Chairman Dr. N. VAN ZANDWIJK presented future responsibilities in the Group :

Secretary : T.A.W. SPLINTER

Vice-Chairman : G. GIACCONE

Chairman of Surgery Subcommittee : P. ROCHMANS

Chairman of Chemotherapy Subcommittee : J.G. McVIE

Chairman of the Radiotherapy Subcommittee : A. GREGOR

Members of the new Publication Committee : O. DALESIO - A. GREGOR - G. GIACCONE - N. VAN ZANDWIJK

Data Center Report

Small Cell Lung Carcinomas

Protocol 08845, conducted in collaboration with Lung Cancer Study Group (NCI) and ECOG, U.S.A : Adjuvant surgery in very limited disease.

Present accrual : 34 patients entered from EORTC, 39 from ECOG and 131 from NCI Lung Study Group. 46% experienced severe (grade III and IV) hematological toxicity.

Protocol 08877 : Alternating versus sequential radio-chemotherapy in limited disease.

Eleven patients randomized ; minimum needed : 30 patients in each treatment arm.

Protocol 08862 : Standard CDE chemotherapy followed by VIMP (carboplatin containing scheme) in extensive disease.

The study is still open and we want to know whether those 2 combinations are really not cross-resistant, please send second-line therapy forms by returning post.

Protocol 08854 : 4'epidoxorubicin in extensive disease patients older than 70 or considered unsuitable for conventional combination therapy (WHO Performance Status of 3).

Thirty-one patients registered ; minimum needed : 40.

Protocol 08873 : teniposide (VM26) in patients with brain metastases.

Thirty-six patients registered, the study now closed to entry ; next draft for a trial comparing teniposide versus teniposide + radiotherapy to be distributed soon.

Non-small cell lung carcinomas

Protocol 08861 : adjuvant therapy in completely resected disease.

Forty-eight patients distributed between trial A (N0, N1 or minimal N2) and trial B (other than minimal N2).

Trial A : 36 patients randomized between radiotherapy and observation.

Trial B : 12 patients randomized between radiotherapy, radio+chemo, observation.

Protocol 08871 : chemoprevention, trial conducted jointly with the EORTC Head and Neck Group. Completely resected non-small cell lung cancer and curatively treated laryngeal and oral cancer randomized to receive intensive screening or not, N-acetyl/cysteine or not and retinol palmitate or not. Nine patients entered by 3 institutions, 5 head and neck tumours, 4 lung tumours.

Protocol 08863 : chemotherapy followed by surgery and radiotherapy in patients with biopsy proven N2 disease.

Poor accrual (4 patients), may be due to the competition with the next 2 protocols.

Protocol 08842 : combination radio/chemo in inoperable limited disease. This very important phase II trial needs 11 more patients to be completed.

Protocol 08844 : cisplatin as radiosensitizer in inoperable limited disease. 285 patients entered; we expect to close the trial at the end of this year. Results of the quality control study now being analyzed by the study coordinators.

Protocol 08875 : phase III trial of teniposide-cisplatin in metastatic disease.

29 patients entered, 15 of them randomized in the arm DDP/VM26 and thus eligible for the NEMESIS trial (protocol 08881 comparing efficacy and tolerability of ICS 205-930 with a metoclopramide-containing antiemetic cocktail for prevention of cisplatin-induced emesis); however it has been decided to open Nemesis not only to patients randomized in 08875 but to patients entered in any protocol including cisplatin (minimum dosage of 50 mg/m²). Forms are now being tested in Amsterdam and as soon as they are judged usable, the study can be activated.

Protocol 08872 : ACNU in advanced small and non-small lung carcinoma.

60 patients entered. One response in the brain reviewed and confirmed. The study is now completed for non-small cell but still open to small cell patients.

Mesotheliomas

Protocol 08878, testing the effects of VP-16 on mesotheliomas is now open, 3 patients have already been registered.

Thymomas

Protocol 08853 : phase II trial with cisplatin/etoposide combination. 9 patients have been entered by 3 institutions. Minimum required : 20 patients.

After the review of ongoing trials Dr. Giaccone presented a draft protocol (Phase II) of TNF in small and non-small carcinoma that according to the wishes of members present, will be finalized and sent to the Protocol Review Committee for a "Quick Procedure".

The Chairman presented an appendix phase III protocol for Gamma-IFN maintenance therapy for small cell patients previously responding on (chemo)therapy. This protocol is not yet in its final form and will be distributed around the Group for comments.

After the formal election of Dr. Splinter as Secretary and the encouragements of the Chairman and to keep an eye open especially to those studies that are not well accruing, the meeting was adjourned.

Next meeting : Roma, January 27 and 28, 1989.

Dr. N. Van Zandwijk

Mrs. A. Kirkpatrick

EUROCODE : A COMPUTER NETWORK FOR ONCOLOGISTS

EuroCODE is an innovative project developed by EORTC under the auspices of the European Economic Community (EEC program "Fight Against Cancer"). The purpose of this project is to facilitate the exchange of information between oncologists, national and international organizations, data centers, and research centers dealing with cancer. In order to achieve this goal, a computerized network accessible to all interested parties has been developed by and implemented at the EORTC Data Center in Brussels on a microVAX II computer.

This computer has now been in operation for two years and offers the following capabilities to the users of EuroCODE :

1. access to a database of EuroCODE users
2. electronic mail between EuroCODE users
3. access to a list of forthcoming cancer meetings
4. access to a database of on-going EORTC clinical trials
5. registration and randomization of patients in clinical trials
6. access to PDQ (Physicians Data Query) (February 1989) No sophisticated equipment is needed to access the EuroCODE network. Any computer terminal or microcomputer can be used with a suitable "modem". The EORTC Data Center can be contacted by potential users for further information (Telephone : (32)(2) 539.30.20)

PDQ (PHYSICIANS DATA QUERY)

PDQ, the US National Cancer Institute's (NCI's) electronic database of cancer treatment information, will be available on EuroCODE early in 1989. This collaborative effort of the EORTC and NCI provides European investigators with up-to-date information on clinical trials and cancer treatment based on current literature. PDQ stands for Physicians Data Query. The purpose of PDQ is to provide current treatment information so that every cancer patient can receive the best standard therapy available and physicians can be informed about relevant investigational trials for their patients. The PDQ database consists of three files : the Cancer Information File, the Protocol File, and the Physician and Organization Directory File. The EORTC has committed to provide NCI with a monthly update of all protocols and investigators participating to EORTC clinical trials. In return, new releases of the PDQ database will be provided by NCI to EORTC on a monthly basis. PDQ will officially be launched on the EuroCODE network in February 1989. EuroCODE will then offer to all European investigators the unique combination of a database with all active investigational protocols and an on-line randomization system for the entry of patients into EORTC trials.