EORTC

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Country: Europe

Group: European Organization for Research and Treatment of Cancer – Breast Cancer Group **(EORTC BCG)**

Chair: Dr H. Bonnefoi
Hopital Cantonal Universitaire de Genève
Department of Gynecology
Rue Micheli-du-Crest, 24
CH-1211 GENÈVE 14
SWITZERLAND
Tel: +41 22 3824013
Fax: +41 22 3824135/7117
Email: herve.bonnefoi@hcuge.ch

EORTC Data Center: Avenue E. Mounier 83, bte 11
B-1200 BRUSSELS
BELGIUM
Tel: +32 2 774 16 11
Fax: +32 2 772 35 45

Website: www.eortc.be

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Title: Postoperative adjuvant chemotherapy followed by adjuvant tamoxifen *versus* nil for node-negative and node-positive patients with operable breast cancer.
EORTC Study No. 10901

Coordinator(s): P.F. Bruning
Antoni van Leeuwenhoek Ziekenhuis
Plesmanlaan 121
NL-1066 CX AMSTERDAM
THE NETHERLANDS
Tel: +31 20 512 25 69
Fax: +31 20 512 25 72

R. Paridaens
Universitair Ziekenhuis Gasthuisberg
Afdeling Gezwelziekten
Herestraat 49
B-3000 LEUVEN
BELGIUM
Tel: +32 16 34 69 02
Fax: +32 16 34 69 01
Email: robert.paridaens@uz.kuleuven.ac.be

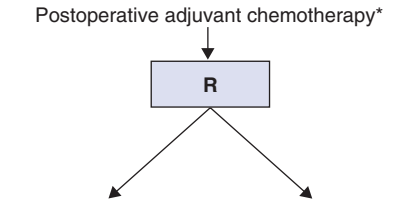
Summary:

- Closed in March 1999 (opened in March 1991)
- Target accrual: 1816 patients

Objectives:

- To investigate the disease-free interval and overall survival after adjuvant chemotherapy followed by tamoxifen compared to chemotherapy alone in patients curatively treated for primary breast cancer with surgery ± radiotherapy.
- To investigate the influence of the estrogen receptor content of the primary tumor on the results of adjuvant treatment as given in this study.

Scheme:



*CMF × 6 or FAC × 6 or FEC × 6 or CAF × 6 or CEF × 6 or AC × 4 or EC × 4

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Update:
- Study closed in March 1999; 1863 patients randomized.

Related Publications:
Please consult our EORTC bibliography website:
http://www.eortc.be/Biblio/default.htm

Publication in progress

Topics:
- Tamoxifen
- Hormone-receptor-positive breast cancer

Keywords: Primary breast cancer, adjuvant hormonal treatment

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Title: Randomized phase III study comparing short, intensive preoperative combination chemotherapy with similar therapy given postoperatively.
EORTC Trial No. 10902

Coordinator(s): N. Tubiana-Mathieu
CHRU de Limoges
Limoges
FRANCE

C.J.H. van de Velde
University Hospital
Department of Surgery
P.O. Box 9600
NL-2300 RC LEIDEN
THE NETHERLANDS
Tel: +31 71 526 23 09
Fax: +31 71 526 67 50
Email: velde@surgery.azl.nl

J.P. Julien
Centre H. Becquerel
1 rue d'Amiens
76038 ROUEN Cedex
FRANCE
Tel: +33 2 32 08 22 12
Fax: +33 2 32 08 22 82

Summary:

- Closed in March 1999 (opened in March 1991)
- Target accrual: 550 patients (100/arm)

Objectives:

- To determine whether preoperative chemotherapy, by reducing the size of the primary tumor will permit more breast conserving therapies.
- To determine the disease-free interval and overall survival in patients who have received preoperative chemotherapy *versus* the same chemotherapy given postoperatively.
- To evaluate the response of the primary tumor to preoperative chemotherapy and correlate this response to disease-free and overall survival.

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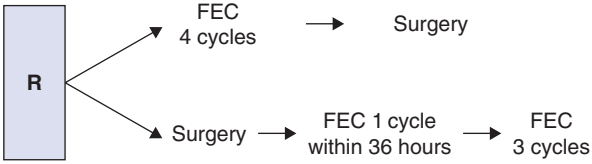
Scheme:



FEC = 600 mg/m^2 5-fluorouracil + 60 mg/m^2 epirubicin + 600 mg/m^2 cyclophosphamide

Update:

- The final results of the study have been published.

Related Publications:

Please consult our EORTC bibliography website: http://www.eortc.be/Biblio/default.htm

Topics:

- Perioperative chemotherapy

Keyword:

Perioperative chemotherapy

https://doi.org/10.1017/S1470903106009126 Published online by Cambridge University Press

Title: Phase III randomized trial investigating the role of internal mammary and medial supraclavicular (IM-MS) lymph node chain irradiation in stage I–III breast cancer (joint study of the EORTC Radiotherapy Cooperative Group and the EORTC Breast Cancer Cooperative Group).
EORTC Study No. 10925/22922

Coordinator(s): W.F. van den Bogaert
Radiotherapy Department
U.Z. Gasthuisberg
Herestraat 49
B-3000 LEUVEN
BELGIUM
Tel: +32 16 346 917
Fax: +32 16 346 901

Dr H. Struikmans
Medisch Centrum Haaglanden – Westeinde
P.O. Box 432 – Lijnbaan 32
NL-2501 CK DEN HAAG
THE NETHERLANDS
Tel: +31 30 250 8800
Fax: +31 30 258 1226
Email: h.struikmans@mchaaglanden.nl

A. Fourquet
Institut Curie
Section Médecine et Hospitalière
Rue d' Ulm 26
75231 PARIS
FRANCE
Tel: +33 144 324 631
Fax: +33 144 324 616

H. Bartelink
Antoni van Leeuwenhoekhuis
Department of Radiotherapy
Plesmanlaan 1121
NL-1066 CX AMSTERDAM
THE NETHERLANDS
Tel: +31 20 512 2122
Fax: +31 20 669 1101

Summary:

- Opened in July 1996
- 4000 patients
- Closed to accrual on 15 January 2004

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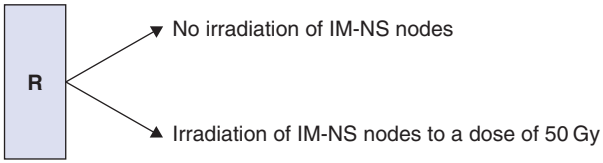
Objectives:

To determine the effect of irradiation to the homolateral mammary supraclavicular lymph node chain in operable breast cancer on:

- Overall survival.
- Disease-free survival.
- Metastases-free survival.
- Cause of death (breast cancer, cardiac, others).

Scheme:



Update:

- Study in follow-up for analysis

Related Publications:

Please consult our EORTC bibliography website:
http://www.eortc.be/Biblio/default.htm

Topics:

- Radiotherapy

Keywords:

Irradiation, internal mammary, medial supraclavicular

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Title: A survey of the Breast International Group (BIG) to assess the attitude of patients aged <35 years, with early breast cancer, toward the risk of loss of fertility related to adjuvant therapies.
BIG 3-98/EORTC 10002

Coordinator(s): A. DiLeo
Sandro Pitigliani Medical Oncology Unit
Dept of Oncology
Hospital of Prato
Piazza dell'Ospedale
59100 PRATO
ITALY
Tel: +39 0574 434 334
Fax: +39 0574 434 246
Email: adileo@usl4.toscana.it

Summary:

- Date of activation: 5 May 2003
- Target accrual: 385

Objectives:

Primary Endpoint:

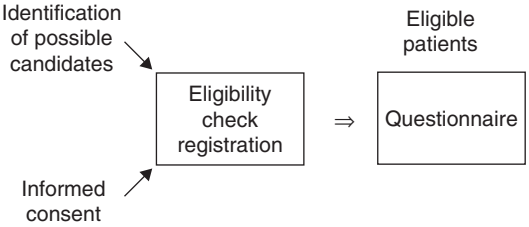
- To estimate the attitude of breast cancer patients toward the risk of sterility related to anti-cancer treatments.

Secondary Endpoint:

- To assess a possible relationship between patient attitude and (a) the fact that the patient already has children and (b) the time interval elapsed between the date of breast cancer diagnosis and the date of study participation.

Scheme: *Eligibility Criteria:*

- Female sex
- Age <35 years at time of breast cancer diagnosis
- Previous or concomitant early breast cancer histologically/cytologically confirmed (stage I or II)
- No evidence of infertility
- No breast cancer relapse



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Update:	• 275 Patients randomized as of 3 October 2006.
Related Publications:	Please consult our EORTC bibliography website: http://www.eortc.be/Biblio/default.htm
Topics:	• Young patients • Fertility and chemotherapy
Keywords:	Sterility, young patients, adjuvant therapy

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Title: LAMANOMA: Conservative local treatment *versus* mastectomy after induction chemotherapy in locally advanced breast cancer: a randomized phase III study.
BIG 2-00/EORTC Study No. 10974/22002

Coordinator(s): Professor J. Jassem
Medical University of Gdansk
Department of Radiotherapy
Ul. Debinki 7
PL-80 211 GDANSK
POLAND
Email: jjassem@amg.gda.pl

Dr E. Van Limbergen
U.Z. Gasthuisberg
Department of Radiotherapy
Herestraat 49
B-3000 LEUVEN
BELGIUM
Email: erik.vanlimbergen@uz.kuleuven.ac.be

Dr G. van Tienhoven
Academisch Medisch Centrum
Department of Radiotherapy
Meibergdreef 9
NL-1105 AZ AMSTERDAM
THE NETHERLANDS
Email: g.vantienhoven@amc.uva.nl

Summary:

- Opened in October 2001
- Target sample size: 1300
- Closed in 29/12/2003

Objectives:

- The main objective is to show that breast conservative treatment (BCT) (exclusive radiotherapy or tumorectomy followed or preceded by radiotherapy) is not inferior to mastectomy plus postoperative radiotherapy in terms of overall survival (primary endpoint) and time to locoregional failure (secondary endpoint) in locally advanced breast cancer patients who first received induction chemotherapy.
- Additionally, quality of life of the two strategies will be compared.

Scheme: *Stratification Factors:*

- Institution
- Initial stage

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- Response to induction chemotherapy
- Menopausal status

Eligible patients will be randomized between BCT arm and mastectomy plus radiotherapy arm.

Update:
- Study closed due to poor accrual.

Related Publications:
Please consult our EORTC bibliography website:
http://www.eortc.be/Biblio/default.htm

Topics:
- Breast conservative treatment
- Locally advanced breast cancer

Keywords:
Breast conservative treatment, mastectomy, radiotherapy

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Title: p53 study: First prospective intergroup translational research trial assessing the potential predictive value of p53 using a functional assay in yeast in patients with locally advanced/inflammatory or large operable breast cancer, prospectively randomized to a taxane *versus* non-taxane regimen.
BIG 1-00/EORTC 10994

Coordinator(s): Dr H. Bonnefoi
Hopital Cantonal Universitaire de Genève
Maternite
Rue Micheli-du-Crest, 24
CH-1211 GENÈVE 14
SWITZERLAND
Email: herve.bonnefoi@hcuge.ch

Summary:

- Study opened to accrual: March 2001
- Target sample size: 1440 updated to 1850 (see amendment 3 to protocol)

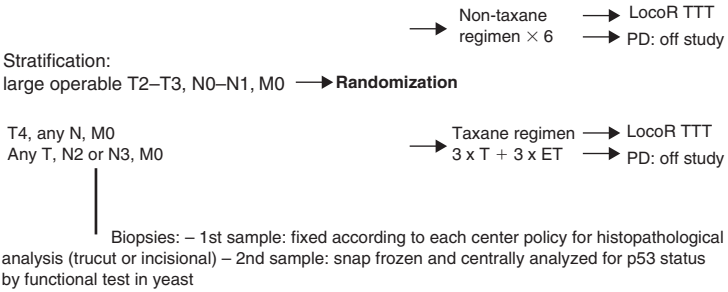
Objectives:

- Compare two chemotherapy arms (arm A: without taxanes and arm B: with taxanes) in the two p53 subgroups separately.
- Test for an overall difference between the two chemotherapy arms.
- Test for interaction between the two chemotherapy arms and the p53 status.

Side Studies:

- Agreement between p53 assessment by IHC method and functional test in yeast.
- Tumor assessment using cDNA microarray technology.

Scheme:



Update:

- 1825 patients randomized as of 3 October 2006.

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Related Publications: Please consult our EORTC bibliography website: http://www.eortc.be/Biblio/default.htm

Topics:
- Taxanes
- Predictive markers
- Locally advanced breast cancer

Keywords: p53, potential predictive factor, taxanes, locally advanced breast cancer, inflammatory breast cancer, large operable breast cancer

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Title: After mapping of the axilla: radiotherapy or surgery AMAROS.
EORTC 10981/22023

Coordinator(s): R. Mansel
University of Wales College of Medicine
Heath Park
CARDIFF, CF14 4XN
UNITED KINGDOM
Email: manselre@cf.ac.uk

Dr E. Rutgers
The Netherlands Cancer Institute – Antoni Van Leeuwenhoekziekenhuis
Plesmanlaan 121
NL-1066 CX AMSTERDAM
THE NETHERLANDS
Email: ERutgers@nki.nl

Professor C. Van De Velde
Leiden University Medical Centre
Albinusdreef 2, Postbus 9600
NL-2300 RC LEIDEN
THE NETHERLANDS
Email: C.J.H.van_de_Velde@lumc.nl

Summary:

- Study opened in February 2001
- Target sample size: 3485

Objectives:

- Prove equivalence in local control between the two treatment modalities of the axilla which reduced the morbidity.
- Prove benefits for all involved parties. Patients will benefit because of the well-controlled use of the sentinel lymph node mapping and the avoidance of unnecessary axillary dissection. This study will yield important information on local control, morbidity, quality of life, and quality of treatment by comparing the different treatment groups.

Scheme: Randomization will take place before the sentinel node procedure. The patient will know before surgery whether she will have a complete axillary dissection or radiotherapy if the sentinel node(s) is (are) tumor positive on frozen section or definitive histology.

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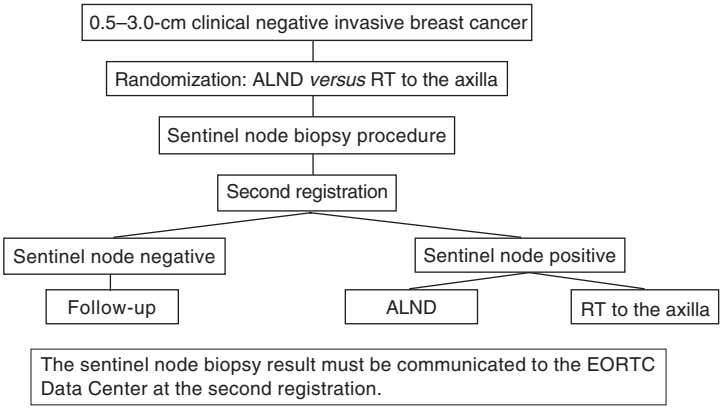

Update:
- 2726 patients randomized as of 3 October 2006.

Related Publications: Please consult our EORTC bibliography website: http://www.eortc.be/Biblio/default.htm

Topics:
- Radiotherapy
- Node-positive breast cancer
- Sentinel node resection

Keywords: Sentinel nodes biopsy, mapping of axilla

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Title: A randomized phase II–III trial evaluating the efficacy of capecitabine and vinorelbine in anthracycline and taxane pretreated metastatic breast cancer.
EORTC 10001/160010

Coordinator(s): M. Piccart
Institut Jules Bordet
Rue Héger-Bordet, 1
BE 1000 BRUSSELS
BELGIUM
Email: martine.piccart@bordet.be

Summary:

- Study opened in September 2002
- Study closed in December 2004
- Target sample size: 72

Objectives:

- The trial is a two arm, randomized phase II study, with extension to a phase III trial if the appropriate statistical criteria are met at the end of the phase II part.

Phase II:

- The principal objective of the phase II trial is to assess the therapeutic activity (as measured by the response rate (RR) using RECIST criteria) of capecitabine and vinorelbine in MBC patients pretreated with taxanes and anthracyclines, or pretreated with taxanes and in whom anthracyclines are medically contraindicated.
- As a secondary objective, the duration of response will be assessed for patients presenting with an objective response.

Phase III:

- The principal objective of the phase III trial is to test for a difference in overall survival in the two treatment arms.
- Secondary objectives are to compare:
  - The progression-free survival (PFS).
  - The time to treatment failure (TTF).
  - Clinical benefit response (CBR) and quality of life (QOL).
  - Overall safety, including adverse events and laboratory abnormalities in both arms.

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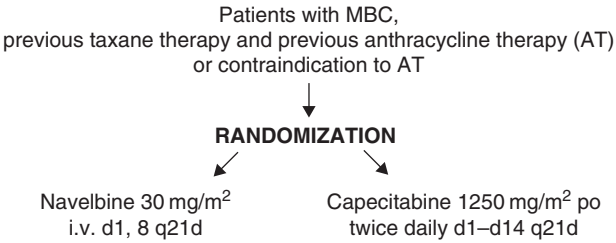
Scheme:



Update:

- The trial was stopped due to poor accrual.

Related Publications: Please consult our EORTC bibliography website: http://www.eortc.be/Biblio/default.htm

Topics:

- Chemotherapy

Keywords: Third line chemotherapy, metastatic breast cancer

https://doi.org/10.1017/S1470903106009126 Published online by Cambridge University Press

Title: Phase I study of lonafarnib (SCH 66336) in combination with Herceptin plus paclitaxel in HER-2 neu overexpressing breast cancer.
EORTC 10051/16023

Coordinator(s): J.H.M. Schellens
The Netherlands Cancer Institute – Antoni Van Leeuwenhoekziekenhuis
Plesmanlaan 121
NL-1066 CX AMSTERDAM
THE NETHERLANDS
Email: jhm@nki.nl

Summary:

- Date of activation: 01/08/2003
- Target sample size: 40
- Main Endpoints: the safety and tolerability profile of the combination through the MTD, the qualitative and quantitative toxicity of the combination, and the recommended dose for phase II.
- Secondary Endpoints: Translational research to document the activity of lonafarnib, pharmacokinetics, pharmacodynamics.

Scheme: Open study with a starting dose of 75 mg twice daily of SCH 66336, 135 mg/m^2 of paclitaxel and 4 mg/m^2 (maintenance 2 mg/m^2) Herceptin. One cycle is 3 weeks. Dose levels are allocated according to a 3 + 3 scheme (3 patients/dose level, up to 6 in case of a DLT). The dose–escalation proceeds in a stepwise manner: for SCH (mg)/PCL (mg/m^2): 75/135, 75/175, 100/175, 125/175, 150/175, 175/175.

Update:

- 23 patients randomized as of 3 October 2006. Patient accrual temporarily interrupted due to administrative issues.

Related Publications: Please consult our EORTC bibliography website: http://www.eortc.be/Biblio/default.htm

Topics:

- HER-2 neu overexpressing breast cancer

Keywords: Lonafarnib, HER-2 neu overexpressing, translational research

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Title: MINDACT trial: A prospective, randomized study comparing the Amsterdam 70-gene expression signature (Mammaprint) with common clinical pathological criteria in selecting patients for adjuvant chemotherapy in node-negative breast cancer.
BIG 3-04/EORTC 10041

Coordinator(s): E.J.T. Rutgers
The Netherlands Cancer Institute – Antoni Van Leeuwenhoekziekenhuis
Plesmanlaan 121
NL-1066 CX AMSTERDAM
THE NETHERLANDS
Email: ERutgers@nki.nl

M. Piccart
Institut Jules Bordet
Rue Héger-Bordet, 1
BE 1000 BRUSSELS
BELGIUM
Email: martine.piccart@bordet.be

F. Cardoso
Institut Jules Bordet
Rue Heger-Bordet, 1
BE 1000 BRUSSELS
BELGIUM
Email: fatima.cardoso@bordet.be

Summary:

- Estimated date of activation: October/November 2006
- Target sample size: 6000
- Stratification for:

– **R-T:** stratifying for institution, risk group (high-risk genetic/low-risk clinical *versus* low-risk genetic/high-risk clinical), HR status (positive (ER and/or PgR) *versus* negative (both)), age ($<$50 *versus* $\geqslant$50), HER-2 (positive *versus* negative *versus* unknown), method of axillary evaluation (sentinel only or dissection), type of surgery (mastectomy or quadrantectomy/tumorectomy).

– **R-C:** stratifying for institution, risk group (high-risk genetic/low-risk clinical *versus* low-risk genetic/high-risk clinical *versus* high-risk genetic/high-risk clinical), HR status (positive (ER and/or PgR) *versus* negative (both)), age ($<$50 *versus* $\geqslant$50), HER-2 (positive *versus* negative *versus* unknown (at the time of R)), method of axillary evaluation (sentinel only or dissection), type of surgery (mastectomy or quadrantectomy/tumorectomy).

– **R-E:** stratifying for institution, risk group (high-risk genetic/high-risk clinical *versus* high-risk genetic/low-risk clinical *versus* low-risk

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genetic/high-risk clinical *versus* low-risk genetic/low-risk clinical), chemotherapy (no chemotherapy, chemotherapy without R-chemotherapy, R-chemotherapy arm A, R-chemotherapy arm B), type of endocrine sensitivity (*both* ER *and* PgR positive *versus either* ER *or* PgR positive), age ($<$50 *versus* $\geqslant$50), HER-2/neu (positive *versus* negative *versus* unknown (at the time of R)), method of axillary evaluation (sentinel only or dissection), type of surgery (mastectomy or quadrantectomy/tumorectomy).

- Main endpoints: R-T: distant metastases-free survival, R-C and R-E: disease-free survival.
- Secondary endpoints: R-T: the proportion of women treated with chemotherapy per treatment decision-making tool, that is clinical prognosis compared to NKI-signature prognosis and overall survival at 5 and 10 years. R-C: overall survival at 5 and 10 years and safety both early and late. R-E: overall survival at 5 and 10 years.

Scheme: Register patients and send tumor biopsy sample for microarray analysis. For those patients who are node negative the genomic prognosis will be performed. Patients with a successful genomic prognostic test are eligible and can be enrolled in MINDACT. After enrollment the two risk assessments (clinical using Adjuvant! Online and genomic using the Amsterdam 70-gene gene signature) are compared and discordant patients are randomized for treatment decision randomization (R-T). Patient who will receive chemotherapy will be offered a further randomization (R-C) between anthracycline-based chemotherapy and docetaxel–capecitabine chemotherapy. Patients with endocrine responsive disease will be offered the endocrine therapy randomization (R-E) between 2 years of tamoxifen followed by 5 years of letrozole or 7 years of letrozole.

Update:
- Approved in the Netherlands and France and in regulatory process for other countries. Trial to open in October/November 2006.

Related Publications: Please consult our EORTC bibliography website: http://www.eortc.be/Biblio/default.htm

Topics:
- Node-negative breast cancer

Keywords: Lymph node-negative early breast cancer, taxotere, capecitabine, letrozole, microarray, prognosis

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