Recherche Clinique en Oncogériatrie

Dr Etienne GC Brain Oncologie Médicale

Hôpital René Huguenin / Institut Curie Saint-Cloud, France

www.siog.org
8842 studies found for:
Open Studies | Interventional Studies | cancer | Adult, Senior | Phase 1, 2, 3

www.clinicaltrials.gov
298 studies found for:
older OR elderly | Open Studies | Interventional Studies | cancer | Senior | Phase 1, 2, 3

www.clinicaltrials.gov

3.4%!!!
Few older adults included in registration studies! Breast cancer as an example

<table>
<thead>
<tr>
<th>Agent Name</th>
<th>Approval</th>
<th>N</th>
<th>Age ≥ 65</th>
<th>N</th>
<th>Age ≥ 75</th>
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<tbody>
<tr>
<td>Palbociclib</td>
<td>2/2015</td>
<td>37</td>
<td>44%</td>
<td>8</td>
<td>10%</td>
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<td></td>
<td></td>
<td>86</td>
<td>25%</td>
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<tr>
<td>Everolimus</td>
<td>7/2012</td>
<td>290</td>
<td>40%</td>
<td>109</td>
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<td>Eribulin mesylate</td>
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<td>Lapatinib</td>
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<td>2</td>
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<td>77</td>
<td>12%</td>
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<td>Ixabepilone</td>
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<td>32</td>
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Package Insert, “Geriatric Usage” section

Courtesy to Arti Hurria (adapted)
<table>
<thead>
<tr>
<th>Year</th>
<th>Study</th>
<th>Description</th>
<th>Age</th>
<th>Phase</th>
<th>Primary Endpoint</th>
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<td>G-01</td>
<td>X+VNR PO breast, lung, prostate</td>
<td>70+</td>
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<td>80</td>
<td>PK</td>
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<td>II</td>
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<td>60</td>
<td>PK</td>
<td>JGO 2010</td>
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<tr>
<td>2004</td>
<td>G-03</td>
<td>per op brachyXRT breast &lt; 3 cm pN0</td>
<td>70+</td>
<td>II</td>
<td>Faisabilité Qualité</td>
<td>40</td>
<td>Cost</td>
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<td>G-04</td>
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<td>II</td>
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<td>27/60</td>
<td>NA</td>
<td>Poster</td>
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<td>G-05</td>
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<td>5/60</td>
<td>NA</td>
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<td>CROH 2010</td>
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<td>validation CRASH Sarcoma Aegide + G-CSF</td>
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<td>Composite</td>
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<td>G-09</td>
<td>breast M+ HER2+++ X + lapatinib Retrospective L1 CT M+ breast (Bergonié) DOGMES L1 DXR lipos (GINECO)</td>
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<td>II R</td>
<td>Composite</td>
<td>4/52</td>
<td>NA</td>
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<td>2010</td>
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<td>CT TxT prostate + PK PRODIGE 20 (G-08)</td>
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<td>II R</td>
<td>Composite</td>
<td>66/60</td>
<td>PK</td>
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<tr>
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<td>CT adj breast RH+ HER2- GGI</td>
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<td>III</td>
<td>OS (competing risks)</td>
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<td>Poster, oral</td>
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<td>2013</td>
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<td>OS + QoL</td>
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<td>XRT/CTneo vs XRT rectum OSAGE (Besançon)</td>
<td>75+</td>
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<td>&gt; 1,000</td>
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<td>70+</td>
<td>III</td>
<td>Outcome + QoL</td>
<td>1,200/2,500</td>
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Need for Distinction between…

1. Non-eligibility
   - Upper age limit & stringent inclusion/exclusion criteria
     • Under-representation and misrepresentativeness

2. Non-invitation (physician’s reluctance)
   - To avoid toxicity & drop out rate; long accrual time; difficulty to handle elderly in trials; belief of less adhesion of elderly to trials; cost increased; institutional support lacking; informed consent

3. Non-inclusion (patient’s decline)
   - Distrust/mistrust; randomization; fear for toxicity, uncertainty; QoL; logistics (cost, transportations); dependence; understanding; fear from patient’s circle of family and friends
Trial Population versus Real-Life

**FIGURE 2** Actual users compared with the clinical trial population

- 0-18 years
- 18-64 years
- ≥65 years

**cl****clinical trial population**

**actual users**
• SEER database
• 3,039 patients ≥ 66, stage IV breast, lung, colon cancer, 2004-2007, bevacizumab
  – Contra-indication defined as 2 claims for thrombosis, cardiac disease, stroke, hemorrhage, hemoptysis, or GI perforation
  – Toxicity defined as 1st development of 1 condition > beva
  – Beva use associated w/ white race, later year of diagnosis, tumor type, and decreased comorbid conditions
  – 35.5% had contra-indication
    • Black race, increased age, comorbidity, later year of diagnosis, lower socioeconomic status, lung and CRC
  – If no contra-indication → 30% complication (black race)
Current dilemma and extreme positions

1. Therapeutic nihilism
   - Elderly patients do not receive any treatment

2. The intermediate position?
   - Elderly patients may benefit from treatments

3. Blind therapeutic enthusiasm
   - Elderly patients receive futile/non beneficial treatments

→ Place and role of geriatrician and oncologist
National Call for Coordinating Units in GO (UCOG) - 2011

- **Aims:** To support national development of GO according to healthcare mapping, including French overseas departments and territories to cover the whole French territory
  1. To better adjust treatments for elderly cancer patients, emphasizing on **shared decision making process** between oncologists and geriatricians
  2. To promote **access to all** in all regions
  3. To strengthen **specific research** (clinical & translational)
  4. To support **teaching and general information**
GERICO
= To use geriatric parameters & items in methods & design

Adding & integrating
Predicting
Screening
Interventions

Real life
Population
Specific criteria
Translational
Ethics
## GERICO ≥ 2,500 patients

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<td></td>
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</tbody>
</table>
Ce qui compte hors cancer

31 patients 75+

## Functional status

**ADL (Katz)**

*Activities of Daily Living*
1. Bathing
2. Dressing
3. Toileting
4. Transferring
5. Continence
6. Feeding

**IADL (Lawton)**

*Instrumental ADL*
1. Ability to use the telephone
2. Shopping
3. Food preparation
4. Housekeeping
5. Laundry
6. Mode of transportation
7. Responsibility for own medication
8. Ability to handle finances

<table>
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<tr>
<th>Decline in ≥ 1 task</th>
<th>2-yr mortality</th>
<th>Need for cares at home</th>
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<tr>
<td>ADL</td>
<td>30%</td>
<td>Full time</td>
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<tr>
<td>IADL</td>
<td>15%</td>
<td>Partial</td>
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</table>

GERICO 06 (EUDRACT N°2005-000069-20, PHRC national 2005)

MC \(\downarrow\) q3w \MC \(\downarrow\) q3w \MC \(\downarrow\) q3w \MC \(\downarrow\) XRT

\textbf{CGA} \textbf{ADL} Tolerance \textbf{ADL} Tolerance \textbf{ADL} Tolerance
\textbf{CGA} \textbf{ADL} Tolerance

\textbf{1 & 2 year DFS & OS}

4 cycles of “AC-like” chemo

In MC, M stands for liposomal non pegylated doxorubicin
Impact of liposomal doxorubicin-based adjuvant chemotherapy on autonomy in women over 70 with hormone-receptor-negative breast carcinoma: A French Geriatric Oncology Group (GERICO) phase II multicentre trial

Etienne G.C. Brain, Cécile Mertens, Véronique Girre, Frédérique Rousseau, Emmanuel Blot, Sophie Abadie, Lionel Uwer, Emmanuelle Bourbouloux, Isabelle Van Praagh-Doreau, Loic Mourey, Sylvie Kirschler, Brigitte Laguérie, Emmanuelle Fourme, Sylvia Luneau, Jean Genève, Marc Debled

1. Febrile neutropenia 15%
2. Risk of denutrition 15% vs 38%
3. Impact on QoL (social & role functioning)
4. Cardiac tolerance of trastuzumab
5. No palmar plantar erythrodysesthesia
6. DFS$_{3A}$ 85%
<table>
<thead>
<tr>
<th>CRASH (Tampa)</th>
<th>City of Hope</th>
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</thead>
<tbody>
<tr>
<td>Chemotherapy Risk Assessment Score for High-age patients</td>
<td>City of Hope</td>
</tr>
<tr>
<td>N pts/centres</td>
<td>585/6</td>
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<tr>
<td>Age</td>
<td>76 (70-92)</td>
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<tr>
<td>Variables</td>
<td>Age, sexe, BMI, DBP&lt;br&gt;Stage, CT &lt;, response, MO&lt;br&gt;CIRSG, polymedication, SRH, PS, IADL, GDS, MMS, MNA&lt;br&gt;CBC, liver, CL\text{\textscript{creat}}, LDH, albumin&lt;br&gt;MAX2 =\frac{(\text{haematol gr 4+ extra-haematol gr 3-4})}{2}</td>
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<tr>
<td>Population</td>
<td>111 chemo regimen</td>
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<tr>
<td>Toxicity</td>
<td>32% grade 4 haematol&lt;br&gt;56% grade 3-4 extra-haematol</td>
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<tr>
<td>Predictors</td>
<td>Haematol: albumin, IADL, LDH, DBP, MAX2&lt;br&gt;Extra haematol: Hb, CL\text{\textscript{creat}}, albumin, SRH, CIRSG, PS, MMS, MNA, MAX2</td>
</tr>
</tbody>
</table>

Ability of (A) risk score versus (B) physician-rated Karnofsky performance status (KPS) to predict chemotherapy toxicity.

Hurria A et al. JCO 2011;29:3457-3465
Risk strata versus toxicity percentage for the (A) development and (B) validation cohorts.

1. 58% grade $\geq 3$ toxicity

2. Risk increased w/ increasing risk score

3. AUC/ROC 0.65 (95%CI 0.58-0.71) ~ development cohort 0.72 (95%CI 0.68-0.77) ($P = .09$)

4. No association between PS and chemo toxicity ($P = .25$)

Arti Hurria et al. JCO 2016;34:2366-2371
Receiver-operating characteristic curves for development and validation cohorts.

Arti Hurria et al. JCO 2016;34:2366-2371
A true predictive model for chemo-related grade 3-5 toxicity
Use of a Comprehensive Geriatric Assessment for the Management of Elderly Patients With Advanced Non–Small-Cell Lung Cancer: The Phase III Randomized ESOGIA-GFPC-GECP 08-02 Study

Romain Corre, Laurent Greillier, Hervé Le Caër, Clarisse Audigier-Valette, Nathalie Baize, Henri Bérard, Lionel Falchero, Isabelle Monnet, Eric Dansin, Alain Vergnègre, Marie Maraq, Chantal Decroisette, Jean-Bernard Auliac, Suzanna Bota, Régine Lamy, Bartomeu Massuti, Cécile Dujon, Maurice Pérol, Jean-Pierre Daurès, Renaud Descourt, Hervé Léna, Carine Plassot, and Christos Chouaïd
Treatment failure–free survival (TFFS) over the duration of the study.

TFFS

Std 3.2 mths

CGA 3.1 mths

(HR 0.91; 95% CI 0.76-1.1)

Romain Corre et al. JCO 2016;34:1476-1483
<table>
<thead>
<tr>
<th>Toxicity</th>
<th>% of Patients</th>
<th>Standard Arm (n = 251)</th>
<th>CGA Arm (n = 243)</th>
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<td>Grade 34 febrile neutropenia</td>
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<td>—</td>
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<td>Grade 3-4 nausea/vomiting</td>
<td></td>
<td></td>
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<td>.46</td>
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<td>1.8</td>
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<td>Grade 3-4 peripheral sensoir neuropathy</td>
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<tr>
<td>All</td>
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<tr>
<td>Monotherapy</td>
<td>1.8</td>
<td>1.3</td>
<td></td>
<td></td>
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<tr>
<td>BSC</td>
<td>—</td>
<td>0</td>
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<table>
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<tr>
<th>Treatment</th>
<th>STD (%)</th>
<th>CGA (%)</th>
<th>P</th>
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<tr>
<td>All grade toxicity</td>
<td>93.4</td>
<td>85.6</td>
<td>.015</td>
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<td>Treatment failure related to toxicity</td>
<td>11.8</td>
<td>4.8</td>
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Co-primary & Composite endpoints

• Co-primary: combine ≥2 primary endpoints (i.e. hierarchy) with dimensions potentially equally/closely weighted – Toxicity/efficacy – Efficacy/functional status

• Composite: combine several criteria in 1 – Cardiology: angina, MI or death – Oncology: death, M+ or LR relapse (DFS) – Treatment success (efficacy/toxicity & compliance): % pts w/ response w/o major AE > n Cy chemo at dose planned and w/o delay

• But

– Correlation between events not always known and measurable

– Sample size

– Mix of events: each event should have the same clinical importance for treatment decision making & describe same clinical issue

– Threshold?

– N events and sample size

– Difficult conclusion if divergent criteria

End Points and Trial Design in Geriatric Oncology Research: A Joint European Organisation for Research and Treatment of Cancer—Alliance for Clinical Trials in Oncology—International Society of Geriatric Oncology Position Article

Hans Wildiers, Muridile Mauer, Athanasios Pallis, Andriu Luciani, Giuseppe Curigliano, Martine Extermann, and Ulrich Wedling, European Organisation for Research and Treatment of Cancer, Brussels; Hans Wildiers, University Hospitals, Leuven and Katholieke Universiteit Leuven, Leuven, Belgium; Hans Wildiers, Arti Harris, Harvey Jay Cohen, and Ulrich Wedling, International Society of Geriatric Oncology, Geneva, Switzerland; Arti Harris, City of Hope, Duarte, CA; Arti Harris, Karla Ballman, Harvey Jay Cohen, and Hyman Muss, Alliance, Chicago, IL; S. P. Koh, G. P. Koh, University of Rochester, Rochester, Stewart M. Lichtman, Memorial Sloan Kettering Cancer Center and Weill Cornell Medical College, New York, NY; Andrea Luciani, S. Paolo Hospital, Giuseppe Curigliano, European Institute of Oncology, Milan, Italy; Martine Extermann, University of South Florida, Tampa, FL; Karla Ballman, Mayo Clinic, Rochester MN; Harvey Jay Cohen, Duke University, Durham, NC; Hyman Muss, University of North Carolina, Chapel Hill, NC, and Ulrich Wedling, Jena University Hospital, Jena, Germany.

Abstract

Selecting the most appropriate end points for clinical trials is important to assess the value of new treatment strategies. Well-established end points for clinical research exist in oncology but may not be as relevant to the older cancer population because of competing risks of death and potentially increased impact of therapy on global functioning and quality of life. This article discusses specific clinical end points and their advantages and disadvantages for older individuals. Randomized or single-arm phase II trials can provide insight into the range of efficacy and toxicity in older populations but ideally need to be confirmed in phase III trials, which are unfortunately often hindered by the severe heterogeneity of the older cancer population, difficulties with selection bias depending on inclusion criteria, physician perception, and barriers in willingness to participate. All clinical trials in oncology should be without an upper age limit to allow entry of eligible older adults. In settings where so-called standard therapy is not feasible, specific trials for older patients with cancer might be required, integrating meaningful measures of outcome. Not all questions can be answered in randomized clinical trials, and large observational cohort studies or registries within the community setting should be established (preferably in parallel to randomized trials) so that treatment patterns across different settings can be compared with impact on outcome. Obligatory integration of a comparable form of geriatric assessment is recommended in future studies, and regulatory organizations such as the European Medicines Agency and US Food and Drug Administration should require adequate collection of data on efficacy and toxicity of new drugs in fit and frail elderly subpopulations.

J Clin Oncol 31, © 2013 by American Society of Clinical Oncology
• **G1 “fit”**
  - None impairment/anomaly
  - CIRSG
    - Grade $\leq 2$
  - (I)ADL normal
  - MNA normal
  - **Standard treatment**

• **G2 “vulnerable” (reversible)**
  - CIRSG
    - $\geq 1$ grade 3
  - $\geq 1$ impaired IADL
  - Risk of denutrition
    - $17 \leq \text{MNA} < 24$
  - **Standard treatment ± geriatric intervention**

• **G3 “frail” (non reversible)**
  - CIRSG
    - $\geq 2$ grade 3 or
    - $\geq 1$ grade 4
  - $\geq 1$ impaired ADL
  - Severe denutrition
    - MNA $< 17$
  - Impaired cognitive functions
    - $15 < \text{MMSE} \leq 24$
  - Desorientation, confusion
  - **Symptoms treatment ± specific actions**

• **G4**
  - Dependance, dementia
  - Major comorbidities
  - Terminal
  - **Palliative cares**
Etude de phase II randomisée d’évaluation de la faisabilité d’une chimiothérapie par docétaxel–prednisone sur un mode hebdomadaire ou toutes les 3 semaines dans une population de patients âgés (+75 ans) « vulnérables » ou « fragiles », définis selon les critères de la SIOG, porteurs d’un adénocarcinome de prostate métastatique réfractaire à la castration et progressif.

Docteur Loïc MOUREY
Feasibility defined as
1. 6 cycles of docetaxel qw or q3w
2. w/o
   • Treatment stop > 2 w
   • Need for dose reduction > 25%
   • Febrile neutropenia or grade 3-4 non haematological toxicity
   • Loss of ADL ≥ 2 points
1) Consultation Oncologique de screening
   - 1ère proposition thérapeutique
   - Vérification des critères d'inclusion dans ELAN-ONCOVAL
   - Note d'information ELAN-ONCOVAL et recueil de la non opposition

2) Si accord, inclusion dans protocole ELAN-ONCOVAL,
   - Recueil 1ère proposition thérapeutique
   - Réalisation questionnaire G8 et recueil 2ème proposition thérapeutique
   - Réalisation Test de Fragilité Gériatrique GERICO : classement fit et unfit et recueil 3ème proposition thérapeutique
   +/- selon les centres : Consultation Gériatrique sous 15 jours et recueil 4ème proposition thérapeutique

3) Consultation de proposition thérapeutique oncologique définitive
   Selon la situation curative ou palliative, et les résultats des tests :

February 2016
Competing causes of mortality

Cumulative probability of death / time of diagnosis

Cumulative probability of death / attained age

Log/log plot of probability of comorbid death vs corresponding probability for cancer-specific death

Deaths attributed to the primary cancer (solid dots) and those attributed to comorbidity (open circles)

Kendal Cancer 2008
Protocol ASTER 70s
GERICO 11 / PACS10

Adjuvant systemic treatment for oestrogen-receptor (ER)-positive HER2-negative breast carcinoma in women over 70 according to Genomic Grade (GG): chemotherapy + endocrine treatment versus endocrine treatment. A French UNICANCER Geriatric Oncology Group (GERICO) and Breast Group (UCBG) multicentre phase III trial

EUDRACT N°2011-004744-22, PHRC national 2011, NCT01 564056
**Group I include both high and equivocal GG cases**

**Randomization stratified on pN, G8 and centre**

**Hypothesis B > A Δ+7.5% (A 80% vs B 87.5%) HR 0.60 α 5% β 10%**
Inclusions on May 19th, 2016

(FR + BE) (48 months)

GERICO11/PACS10

Current Patients randomized (GG 3 or GG EQ)
Inclusion (planned)
Randomisation (initially planned)
Current Patients Included
Randomisation (planned after Amel 1)

Number of Patients

1,989
1,089
Main Inclusion Criteria

- Women aged ≥ 70 yo
- Histologically proven invasive breast cancer (regardless of the type)
- Complete surgery performed before enrolment
- Any N status (pN+ or pN0)
- No clinically or radiologically detectable metastases (M0)
- RE+ and HER2-
  AND !!!!
  - No high selection according to previous medical history
  - Contralateral BC, invasive BC after ductal carcinoma in situ or isolated local invasive relapse eligible
  - Patients with multifocal or bilateral disease eligible
(Pré)Screening, pilot study 390 patients 70+ in ASTER 70s

<table>
<thead>
<tr>
<th>Item</th>
<th>N</th>
<th>%</th>
<th>@227 pts</th>
</tr>
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<tbody>
<tr>
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<tr>
<td>Team choice</td>
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<td>40</td>
<td>44</td>
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<td>Logistics</td>
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<td>17</td>
<td>18</td>
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<td>21</td>
<td>11</td>
</tr>
<tr>
<td><strong>Invited</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Acceptance</td>
<td>175</td>
<td>58</td>
<td>66</td>
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<tr>
<td>Refusal</td>
<td>129</td>
<td>42</td>
<td>34</td>
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Geriatric intervention

- Pennsylvania, follow up 44 mths
- Surgery for cancer 2/1993-12/1995

60+ yo

Standard

Intervention: 3 visits at home + 5 phone calls by trained nurses

<table>
<thead>
<tr>
<th></th>
<th>Standard</th>
<th>Intervention</th>
<th>( p )</th>
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<tr>
<td>( N )</td>
<td>185</td>
<td>190</td>
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</tr>
<tr>
<td>Advanced stage (%)</td>
<td>26</td>
<td>38</td>
<td>0.01</td>
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<tr>
<td>Death (%)</td>
<td>28</td>
<td>22</td>
<td>0.02</td>
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<tr>
<td>2-yr OS early stage (%)</td>
<td>88</td>
<td>90</td>
<td>NS</td>
</tr>
<tr>
<td>2-yr OS late stage (%)</td>
<td>40</td>
<td>67</td>
<td>&lt; 0.05</td>
</tr>
</tbody>
</table>

COX HR 2.04 (IC95% 1.33-3.12, \( p = 0.001 \))

McCorkle JAGS 2000
Nutritional Advice in Older Patients at Risk of Malnutrition during Treatment for Chemotherapy: A Two-Year Randomized Controlled Trial

Isabelle Bourdel-Marchasson1,2,3, Christelle Blanc-Bisson1, Adélaïde Doussau4,5, Christine Germain6, Jean-Frédéric Blanc6,7, Jérôme Dauba6, Cyril Lahmair8, Eric Terrebonne9, Cédric Lecaillée10, Joël Ceccaldi11, Laurent Cany12, Sandrine Lavau-Denes13, Nadine Houede14, François Chomy14, Jessica Durrieu1, Pierre Soubeyran14,7, Pierre Senesse15,16, Geneviève Chene4,5, Mariane Fonck14

1 CHU Bordeaux, Clinical Gerontology, Bordeaux, France, 2 CNRS, IRMAB, UMR 5536, Bordeaux, France, 3 Université Bordeaux, IRMAB, UMR 5536, Bordeaux, France, 4 CHU Bordeaux, Unité d’épidémiologie clinique, Bordeaux, France, 5 INSERM, CIC-ECL, Bordeaux, France, 6 CHU Bordeaux, Hépato-gastroentérologie, Bordeaux, France, 7 Université Bordeaux, Bordeaux, France, 8 Centre Hospitalier Laennec de Marseille, Service Oncologie, Mont de Marsan, France, 9 CHU Bordeaux, Service Hépato-gastro et oncologie digestive, Bordeaux, France, 10 Polyvalent du Nord, Service hépato-gastroentérologie, Bordeaux, France, 11 CHU Bordeaux, Centre Hospitalier de Libourne, Libourne, France, 12 Clinique Francheville, Périgueux, France, 13 CHU Limoges, Unité de recherche clinique en oncologie médicale, Limoges, France, 14 Université Bordeaux, Université de Bordeaux 1 et 3, Laboratoire Epsion EA 4556, Montpellier, France, 16 CICCC du Val d’Aurelle, Unité de Nutrition clinique et de gastroentérologie, Montpellier, France

Abstract

Objective: We tested the effect of dietary advice dedicated to increase intake in older patients at risk for malnutrition during chemotherapy, versus usual care, on one-year mortality.

Method: We conducted a multicentre, open-label intervention, stratified (centre), parallel randomised controlled trial, with a 1:1 ratio, with two-year follow-up. Patients were aged 70 years or older treated with chemotherapy for solid tumour and at risk of malnutrition (MNA, Mini Nutritional Assessment 17–23.5). Intervention consisted of diet counselling with the aim of achieving an energy intake of 30 Kcal/kg body weight/d and 1.2 g protein/kg/d, by face-to-face discussion targeting the main nutritional symptoms, compared to usual care. Interviews were performed 6 times during the chemotherapy sessions for 3 to 6 months. The primary endpoint was 1-year mortality and secondary endpoints were 2-year mortality, toxicities and chemotherapy outcomes.

Results: Between April 2007 and March 2010 we randomised 341 patients and 336 were analysed: mean (standard deviation) age of 78.0 y (4-9), 51.2% male, mean MNA 20.2 (2.1). Distribution of cancer types was similar in the two groups the most frequent were colon (22.4%), lymphoma (14.9%), lung (10.4%), and pancreas (17.0%). Both groups increased their dietary intake, but to a larger extent with intervention (p<0.01). At the second visit, the energy target was achieved in 57 (40.4%) patients and the protein target in 66 (46.8%) with the intervention compared respectively to 13 (13.5%) and 20 (20.8%) in the controls. Death occurred during the first year in 143 patients (42.5%), without difference according to the intervention (p = 0.79). No difference in nutritional status changes was found. Response to chemotherapy was also similar between the groups.

Conclusion: Early dietary counselling was efficient in increasing intake but had no beneficial effect on mortality or secondary outcomes. Cancer cachexia anabiosis may explain this lack of effect.

Trial Registration: ClinicalTrials.gov NCT00459589
Nutritional vs standard: 1-yr mortality 70+ w/ MNA 17–23.5
341 patients enrolled/820 planned → power!
CRC (22.4%), NHL (14.9%), lung (10.4%), pancreas (17.0%)

<table>
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<tr>
<th></th>
<th>Usual Care</th>
<th>Usual Care + Nutritional Intervention</th>
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<tr>
<td></td>
<td>N = 167</td>
<td>N = 169</td>
<td></td>
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<tr>
<td>Incident fall, pressure ulcer or fracture, % (n)</td>
<td>6.0 (9)</td>
<td>5.6 (9)</td>
<td>0.87</td>
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<tr>
<td>Infection grade 3-4, % (n)</td>
<td>10.4 (7)</td>
<td>42 (7)</td>
<td>0.03</td>
</tr>
<tr>
<td>Hospitalisation, % (n)</td>
<td>34.4 (56)</td>
<td>29.1 (48)</td>
<td>0.31</td>
</tr>
<tr>
<td>Enteral/parenteral nutrition, % (n)</td>
<td>9.2 (15)</td>
<td>5.5 (9)</td>
<td>0.19</td>
</tr>
</tbody>
</table>
• Review 2005-2012 (National Call PHRC)
  – Number of projects
    • 27/479 (6%)
  – 400 patients → 2,400 patients
  – 1% of eligible population (vs 7.5% for the rest of the population)
  – Funding
    • 7,5/139 M€ (6%)
• All calls include GO!!!
• « Action 2.16 : Améliorer la prise en charge des personnes âgées atteintes de cancer et la prise en compte de leurs besoins spécifiques, notamment en s’appuyant sur une recherche clinique renforcée pour cette population. La prise en charge des personnes âgées, caractérisées par plusieurs éléments de fragilité dans la prise en charge du cancer (polypathologies fréquentes, difficultés de mobilité), est une priorité »
To demonstrate the impact of geriatric assessment on cancer prognosis in the elderly cancer population?

- **PREPARE program (French PHRC 2013-2014)**
  - Initial cares with first or second line chemotherapy
    - L1: breast, colorectal gastric, lung, prostate, bladder, ovarian, myeloma, NHL
    - L2: breast, colorectal, prostate, myeloma, NHL
  - Primary endpoint: 1-yr OS (+10%) & HrQoL (+10 points)

> 70A
L1 or L2 → G8

> 14 → Standard treatment

≤ 14 → R 1:1

Case management ("G8-guided", nurse, geriatrician, etc.)

Soubeyran PHRC 2013-2014
Two worlds confronting one another?

**Young patient**
- Social and family obligations (children)
- Quantity of life +++

**Elderly patient**
- QoL+++
- Independence
- Staying at home

**Oncology**
- Therapies and innovation
- Toxicity, response
  - RECIST
  - NCI CTC v4.0
  - Survival (DFS, PFS, OS)
- Fast-moving world
- "Molecular portrait" of tumour & GEP

**Geriatrics**
- Symptoms, diagnosis
- Quality of survival, i.e. amount of life with good QoL
  - Cognition
  - Functional status
  - QoL
  - Nutrition, etc.
- Requiring time
- "Global portrait" of patient & CGA
Priorities?

1. CGA: **impact on cancer prognosis** → PREPARE
2. RX in "older elderly" (75+, octogenarians, nonagenarians, centenarians)
3. RX in **vulnerable** (reversible) vs **frail** (non reversible) patients
4. **De-escalation** questions
5. **Minimal** geriatric assessment
6. **Specific** primary endpoints (derived from CGA, composite, co-primary)
7. **Translational research** (cancer and ageing)
8. **International** collaboration

**Intergroup GERICO/UCOG (DIALOG)**
(clinical research in geriatric oncology)
labeled by INCa in 2014
DIALOG Minimal Data Set (Delphi/RAND + Consensus Methods)

- Living alone? Care giver? ± living in institution/nursing house?
- ADL + mini-IADL (4 items)
- Gait (walking) speed OR Timed get up and go test
- MNA-SF OR 3-month loss of weight + IMC
- 5 words of Dubois (uncertain) + Clock test OR Mini-COG
- Mini-GDS (4 items)
- Updated Charlson Comorbidity Index

Relative
No consensus
Strong
Relative
Relative
Relative
No consensus
Relative
Relative
Relative

Second run of assessment & oncologist panel
From a "prejudice-based" to an "evidence-based" medicine...

- 10 institutions CALGB
  - 77 « paires » cancer du sein (< 65A vs > 65A)
  - Etude des cas de propositions d’essai

<table>
<thead>
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<th></th>
<th>&lt; 65A</th>
<th>&gt; 65A</th>
<th>p</th>
</tr>
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<tbody>
<tr>
<td>I</td>
<td>11/35 (31)</td>
<td>13/40 (33)</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>22/34 (68)</td>
<td>11/29 (38)</td>
<td>0.0004</td>
</tr>
<tr>
<td>IV</td>
<td>2/2 (100)</td>
<td>1/2 (50)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>36/71 (51)</td>
<td>25/71 (35)</td>
<td></td>
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</tbody>
</table>

- Analyse multifactorielle : stade, âge (comorbidités contrôlées)
- Aucune différence de participation si proposition +++ : 56% vs 50%
FEC, AACR, FAC, ASCO, anti-PDL1, anti-PD1, CMF, SABCS, PD-1, PDL1, DXR, PK/PD, CEX, 5FU, CDDP, Calvert AUC, ESMO, Chatelut AUC, CTC, TILs, population PK, EORTC, FOLFIRI, ctDNA, FOLFOX 7, CPA, DFS, CALGB, DDFS, OS, TTP, NCI, CYP P450, JCO, JNCI, HER2, PI3K, mTOR, Phase 0, ECCO, ib and ab, Unicancer, EORTC, SWOG, CALGB, etc.

Charlson, CIRSG, CGA, AD, MCI, MNA, GDS, MMS, ADL, IADL, GFI, CMR2, JAGS, EUGMS, G8, CARG, Oncodage, VES-13, TRFs, JGO, NIA, SoFOG, Walter’s score, Lee’s score, CRASH, etc.
To be practice changing, let us be practice sharing!
Join our unique CME accredited training programme lead by international experts in the field of geriatrics AND oncology designed to provide specific skills in assessment, care pathways and therapeutic choices about the elderly patients with cancer in order to provide the basis of the assessment and the multi-dimensional approach that should be applied to elderly cancer patients.

Oncologists and Geriatricians need to work together! Here is how:

Admission process opens on January 9, 2017
Find out more at www.siog.org

Course director: Silvio Monfardini (IT)
Course co-director: Etienne Brain (FR)
Course coordinator: Giuseppe Colloca (IT)

This course is an ESO recommended activity and is held with the support of

Pending auspices and endorsements:
17th SIOG Annual Conference, Warsaw - Poland

SAVE THE DATE - November 9-11, 2017

www.sioog.org