

Mamma en colorectale studies

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BOOG 2006-02: OMEGA



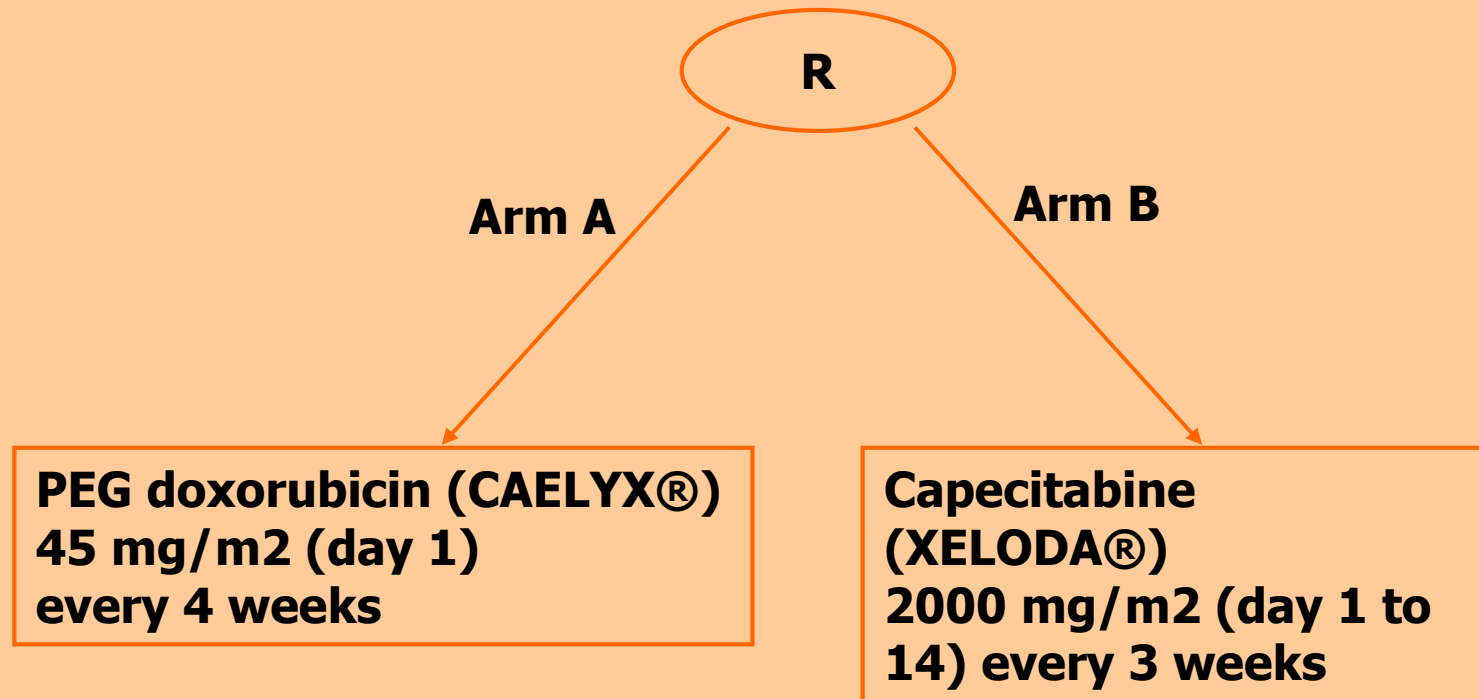
Phase III study comparing Capecitabin (Xeloda) vs PEG Doxo (Caelyx) as 1st line chemotherapy in Older METastatic BC patients (> 65 yr), Including a Geriatric Assessment

Steering group:

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Darbepoetin (Aranesp): if HB < 6.8 mmol/l (target HB 7.4 mmol/l)
500 mcg or 300 mcg

G-CSF: discretion of the investigator

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Therapy duration:	24 weeks (6 or 8 cycles)
QoL / Geriatric assessment:	baseline, 12 wks, 24 wks, + 52 wks
	Co-morbidity, Co-medication, Sociodemographics
	Functional status (IADL + PS)
	QoLQ-C30
	GFI
	Depression (GDS 15), Cognition (MMSE)
Response Evaluation:	every 12 weeks
Follow-up post Rx:	every 12 weeks
Sample size:	154 evaluable patients

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Study Objectives:

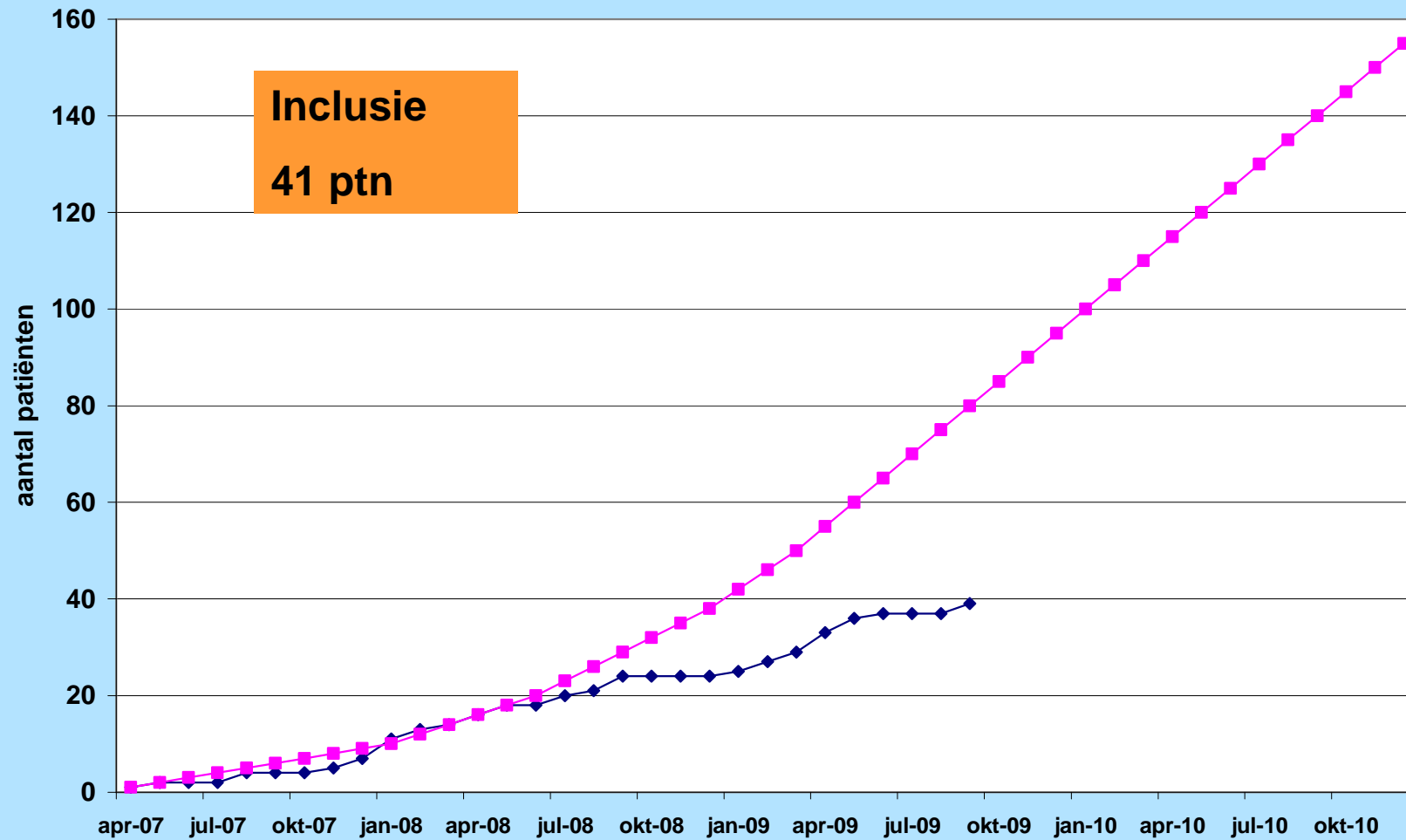
- *Primary:* Progression Free Survival
- *Secondary:*
 - Objective Response Rate, Clinical Benefit
 - Overall Survival
 - Relation with co-morbidity and co-medication
 - Value of GA
 - Predictive of toxicity ? Response ?
 - Value of GFI ?
 - Optimal GA: CGA, GFI or PS ?
 - W.r.t. selection of patients who will benefit from chemotherapy or will be able to support chemotherapy
 - Toxicity / tolerability / compliance of the 2 treatment regimens

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Status

- METC: centrale goedkeuring MC Alkmaar
lokale goedkeuring in 20 centra
ingediend in 3 centra
8 geïnteresseerden
- Geactiveerd: februari 2007
- CAELYX: vrij verstrekt
- Toxiciteit: relatief weinig Gr 3,4
waarvan deels al bij aanvang hoog (Hypertensie, dyspneu)

Aantal patiënten in de OMEGA studie (t/m okt 2009)





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TLC study

Bi-daily Tegafur-uracil plus Leucovorin vs Capecitabine as first-line therapy in elderly with advanced colorectal cancer, unfit or unwilling for combination chemotherapy

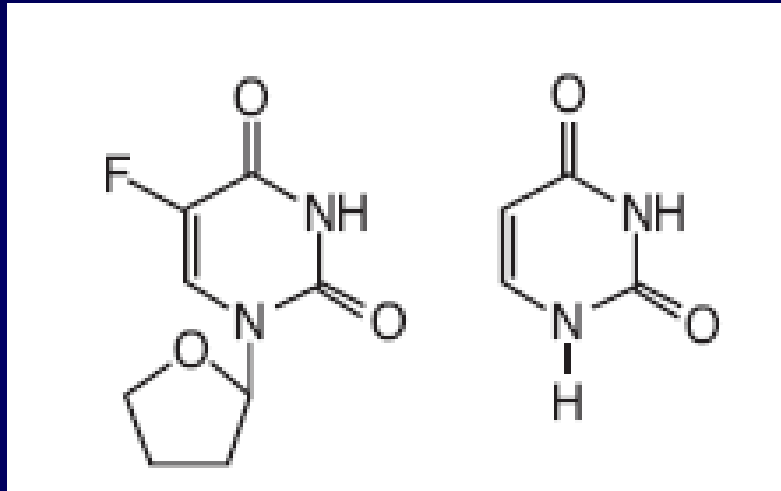
- A randomized, open label phase III study -



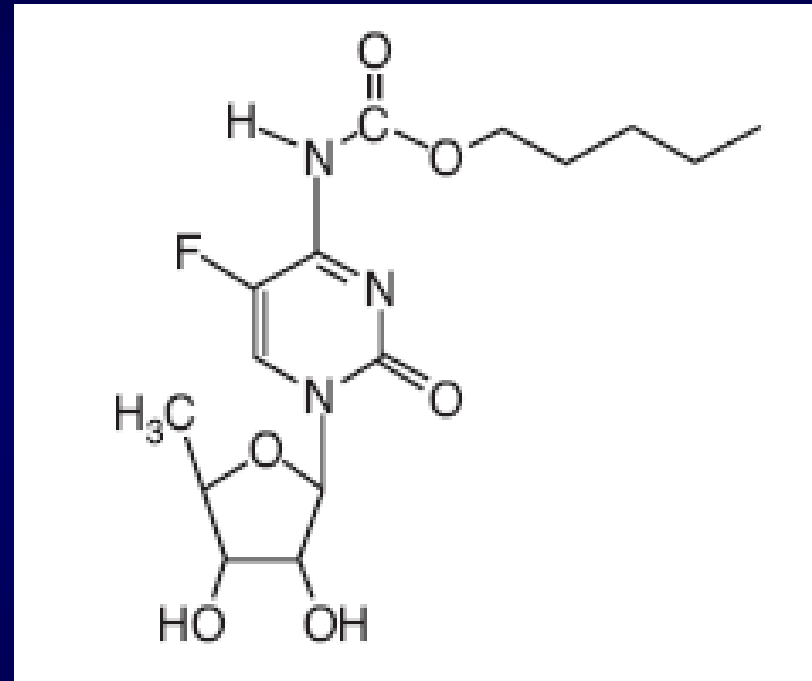
Background TLC

- **CRC is most often diagnosed in elderly pts**
- **Elder CRC pts have similar benefit from chemotherapy as younger pts**
- **In elderly, often with co-morbidity, combination chemotherapy may be associated with more toxicity and less overall benefit.**
- **UFT and capecitabine are both ideal for monotherapy, but have never been compared in a randomised trial.**

TLC drugs



**Tegafur - uracil
(UFT)**



Capecitabine

Oral vs parental fluoropyrimidines

- **Equivalent efficacy**
- **Favourable safety**
- **Patient convenience (oral, b.i.d)**
- **Lower costs**

Favorable toxicity as compared to 5FU

UFT

- Less neutropenia
- Less stomatitis/mucositis
- Less fever and infection

Douillard J et al, JCO, 2002

Carmichael j et al, JCO,2002

Capecitabine

- Less neutropenia
- Less stomatitis/mucositis
- Less fever and infection
- More hand-foot syndrome

Hoff PM et al, JCO, 2001

Van Cutsem E et al, JCO, 2001

Treatment schedule

Arm A:

- UFT 300 mg/m² orally, divided in 2 daily doses, days 1-28
- LV 60 mg/day orally, divided in 2 daily doses, days 1-28
- Q5 weeks

Arm B:

- Capecitabine 2500 mg/m² orally, divided in 2 daily doses, days 1-14
- Q3 weeks

CGA in TLC

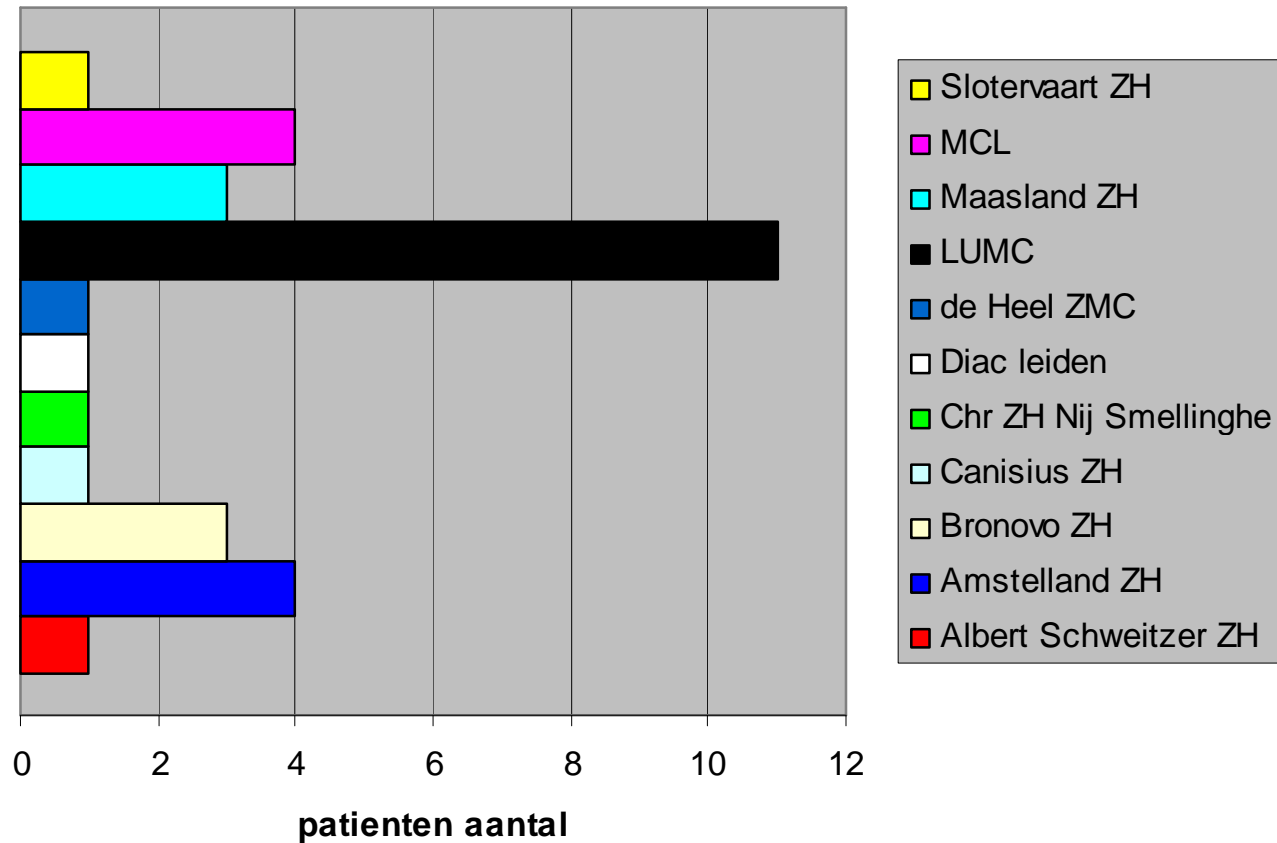
- **Charlson co-morbidity index (at randomisation)**
- **Instrumental Activities of Daily Living (IADL)**
- **Geriatric Depression Score (GDS)**
- **Groningen Frailty Indicator (GFI)**
- **Quality of Life (QoL)**

***Patient vult zelf CGA in. Eerste CGA retour naar NKI
waarna de CGA's naar pts worden gestuurd!***

Wat doet de arts

- **Vraagt IC**
- **Vraagt co-morbiditeit**
- **Stuur CGA 1e keer retour naar NKI**
- **Controle patiënt voor elke kuur (elke 3 of 5 weken)**
- **Response evaluatie elke 9 weken**
- ***Optioneel: eenmalig afname EDTA (-20°C bewaren) en stolbuis (na centrifugeren plasma bij -20°C bewaren)***

Inclusie TLC november 2009



Elderly have the future

