

**Name der Studie:**

Kontinuierliche Gabe von Fluorouracil plus Mitomycin C versus Mitomycin C plus Cisplatin als Chemotherapie Kombination in kombinierter Radiochemotherapie für das lokal fortgeschrittene Analkarzinom. Phase-II-III-Studie (EORTC 22011- 40014)

Studienleiter:

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Studienzentrum:

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Kurzbeschreibung der Studie:

The currently proposed randomized trial aims at comparing the optimized 5-FU-MMC treatment to a similar regimen where the chemotherapy with 5-FU and MMC is replaced by a combination of MMC and Cisplatin (CDDP). The effects of this treatment on anal sphincter function and quality of life will be prospectively evaluated as a secondary endpoint in this study.

Ziel der Studie:**Phase II**

The objective of the phase II part of the trial is to demonstrate that irradiation (XRT) and chemotherapy (CT) using Mitomycin C (MMC) and Cisplatin (CDDP) is feasible and that this regimen can achieve a similar early clinical response (judged 8 weeks after treatment completion), as the same XRT scheme and CT using MMC and continuous 5-FU.

Phase III

The objective of the phase III part of the trial is to compare the efficacy of the experimental treatment with MMC - CDDP combined XRT-CT treatment to that of the new standard combined XRT-CT treatment for locally advanced anal canal carcinoma. The hypothesis being tested is that the experimental treatment (MMC - CDDP) will be superior to MMC - 5 -FU in terms of the event free survival (survival without progression nor colostomy).

Art der Studie:

- prospektiv
 randomisiert
 unizentrisch

- einfache Verblindung
 doppelte Verblindung
 multizentrisch

Wesentliche Einschlusskriterien:

- _ Histologically proven squamous cell anal carcinoma (all types of squamous cell carcinoma are eligible, keratinising or non keratinising)
- _ Tumour located in the anal canal or in the anal margin and infiltrating the anal canal (primary adenocarcinomas of the anal cancer and tumors arising at the anal margin and not infiltrating the anal canal are not eligible)
- _ The following stages are eligible (UICC 1997, see Appendix H)
 - the subgroup of T2 N0 tumors with maximum diameter equal or greater than 4 cm (≥ 4 cm)
 - T3 N0
 - T4N0
 - N1 anyT
 - N2 anyT
 - N3 anyT
- _ M0 disease
- _ Measurable disease (according to RECIST definition, see chapter 7.1.1.1.1.)
- _ Age 18 to 75 years
- _ WHO performance status 0 or 1 (Appendix B)
- _ Creatinine $< 120 \mu\text{mol/l}$
- _ Granulocytes $> 2 \times 10^9/\text{l}$
- _ Platelets $> 100 \times 10^9/\text{l}$

Wesentliche Ausschlusskriterien:

- _ No prior treatment for the anal cancer
- _ No prior colostomy
- _ No previous history of malignant disease (except adequately treated basal cell carcinoma of the skin and in situ carcinoma of the uterine cervix)
- _ No history of Grade I angina pectoris with clinical symptoms, nor grade II, III or IV angina pectoris (irrespective of the presence of clinical symptoms) during the past 3 months (according to the Acute Coronary Artery Disease Grading System of the Canadian Society, see Appendix I).
- _ No history of distal arteritis stage II or more according to the Leriche and Fontaine classification (see Appendix J)
- _ No pregnant or breast feeding women and no fertile patients (M/F) without adequate contraception

_ Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule;

Weitere beteiligte Kliniken / Studienzentren:

Cliniques Universitaires St. Luc (Brussels, Belgium) - Inst. 121
U.Z. Gasthuisberg (Leuven, Belgium) - Inst. 147
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Centre Hospitalier Universitaire Vaudois (Lausanne, Switzerland) - Inst. 457
Dr. Bernard Verbeeten Instituut (Tilburg, The Netherlands) - Inst. 341
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Geplanter Studienbeginn:

Juli 2003

Geplante Studiendauer:

6,5 Jahre

Geplante Rekrutierungsanzahl:

Phase II: 68 Patienten Phase III: 678 Patienten

Förderung: Ja

nein

Wenn Ja, durch:

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