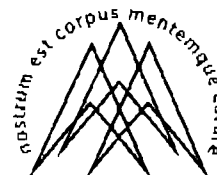


# Zentrum für onkologische, endokrinologische und minimalinvasive Chirurgie



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## Final Report Ukrain Study

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This study started in October 1999. In June 2001 the study was closed, in each arm 30 patients were recruited.

Arm A (Gemcitabine)

Arm B (Ukrain®)

Arm C (Gemcitabine + Ukrain®)

In each study arm 2 drop outs were noted. These patients were not taken into the final results in March 2003.

Regarding the patients data, see publication (Gansauge et al., Langenbeck's Archives of Surgery (2002) 386: 570-574).

In arm A (Gemcitabine monotherapy) all patients have died, in Arm B (Ukrain® monotherapy) 2 patients are alive (7,1%) 26 and 28 months after start of the therapy, in arm C (Gemcitabine + Ukrain®) all patients have died.

Regarding the side effects and the assessment of quality of life see publication (Gansauge et al., Langenbeck's Archives of Surgery (2002) 386: 570-574).

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**Median Survival (Kaplan-Meier-Lifetime analysis)**

Arm A (Gemcitabine monotherapy)	4,8	months
Arm B (Ukrain® monotherapy)	8,1	months
Arm C (Gemcitabine + Ukrain®)	9,3	months

**Significance levels (Chi-square-test)**

Arm A versus Arm B:	$p < 0,01$
Arm A versus Arm C:	$p < 0,02$
Arm B versus Arm C:	not significant ( $p=0,67$ )

**Survival rates**

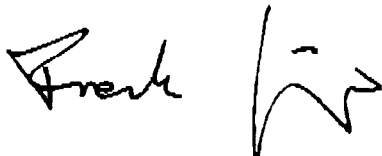
	6 months	9 months	12 months	24 months
Arm A	32%	11%	11%	0%
Arm B	61%*	43%**	32%	18%
Arm C	64%*	54%**	29%	4%

## Summary and Conclusion

In this analysis at the end of the study „Ukrain® in the palliative treatment of advanced pancreatic cancer patients“ the preliminary results were confirmed. The median survival times in arm C were reduced as compared to the study results 18 months ago, whereas median survival times remained unchanged in arm A and arm B.

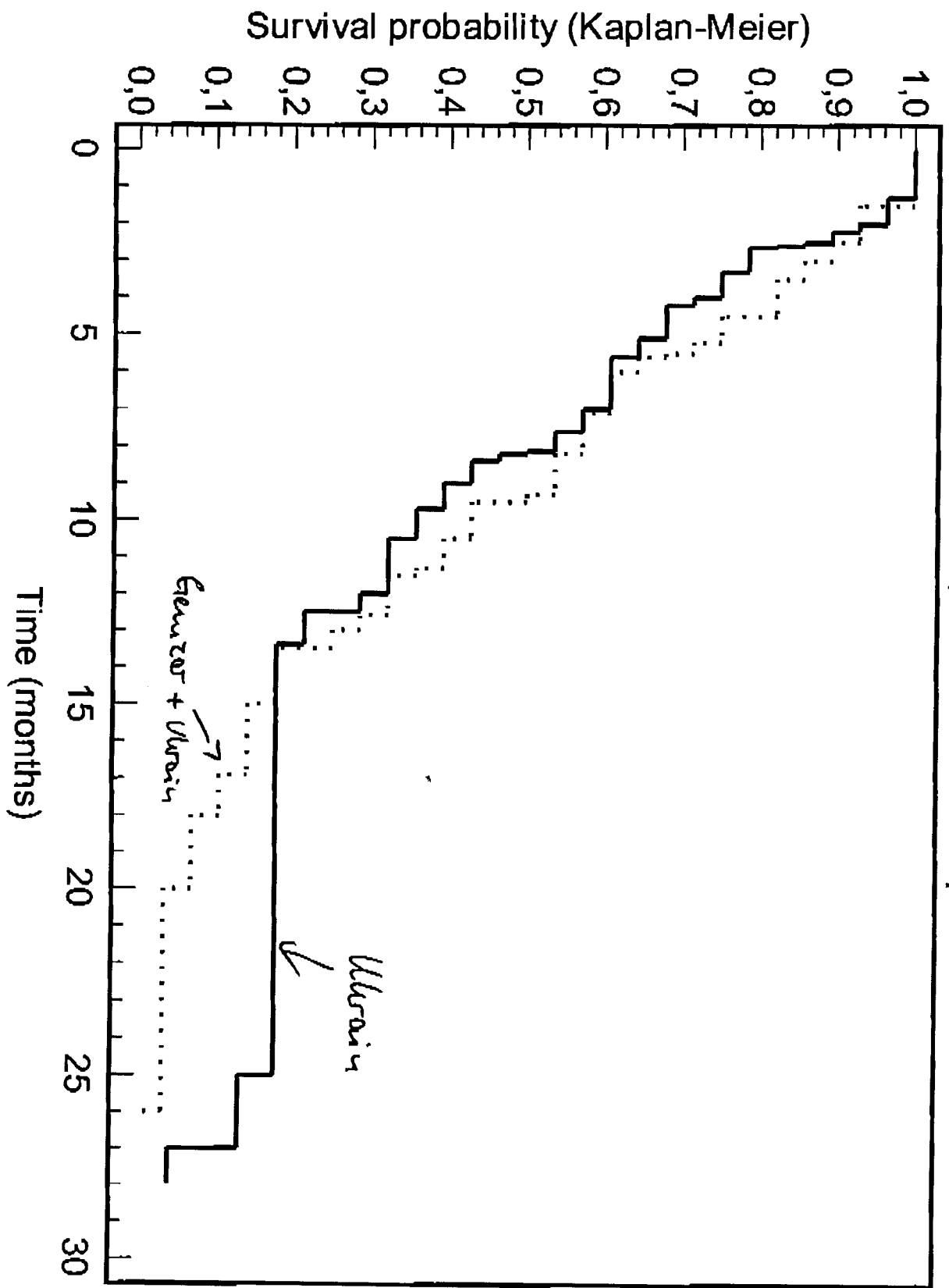
Ukrain® proofed to be well tolerated and can be used easily on an outpatient basis. In the study arms containing Ukrain® the median survival times were significantly prolonged as compared to the Gemcitabine monotherapy arm. The combination of Gemcitabine with Ukrain® showed no significant advantage as compared to the Ukrain® monotherapy arm. As the result of this study we highly recommend the treatment of patients suffering from advanced pancreatic cancer with Ukrain®.

Neu-Ulm, 13.03.2003

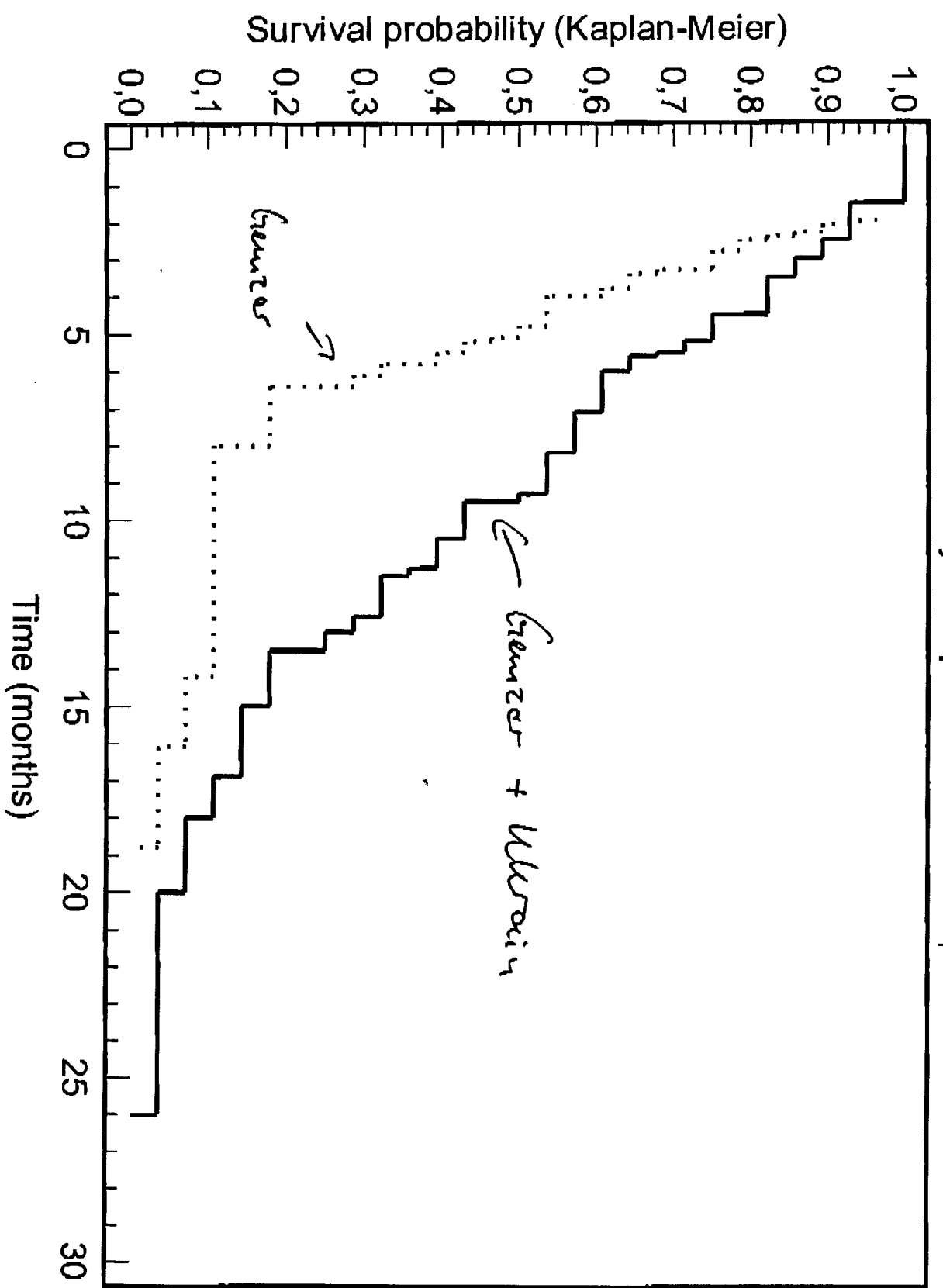


Frank Gansauge, MD, PhD

Survival in pancreatic cancer patients



# Survival analysis in pancreatic cancer patients



# Survival in pancreatic cancer patients

