Prospective phase II trial for recurrent high-grade gliomas with low radiofrequency (LRF) hyperthermia

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Background: In spite of many new approaches the treatment of malignant gliomas is still disappointing. Concomitant radiotherapy with temozolomide could improve in a RCT median survival of pts with glioblastoma multiforme from 12.1 to 14.6 months (EORTC *26981-22981; NCIC,3; ASCO 2004*). About 20% of pts with gliomas benefit from therapy depending on genomic mutations. Deep Hyperthermia with low-radiofrequency coupled-electrodes (LRF-DHT) with 13.56 MHz is feasible in treating pts with brain tumors (*Hager ED et al., ASCO 2003,#470*). 4/5 of the effective RF-energy can induce selectively apoptosis in cancer cells instead of heat. Heat alone would be contraindicated for the treatment of tumors in the brain. Therefore, elctro-hyperthermia (EHT) is also referred to this technique.

Methods: N=179 pts with highly-malignant gliomas (WHO grade III/IV at 1st diagnosis) where treated with LRF-DHT after recurrence of the disease after surgery, radiotherapy and/or chemotherapy. N= 53 Pts in the astrocytoma WHO grade III group) and N=126 pts in the WHO grade IV group (glioblastoma multiforme), KI >50%, where analysed in an intention-to-treat observational study. Recrutation time was from 02/2000 to 04/2007.

Results: Complete data where collected from all pts and considered for evaluation if at least 1 cycle of LRF-DHT could be performed. The median overall survival times (MST) are listed in table 1. Longstanding complete and partial remissions could be achieved after recurrence in both groups.

Conclusions: LRF-DHT is feasible in treating pts with highly malignant gliomas without any severe side effects. Hyperthermia may increase overall median survival time (MST) by about 6 months after recurrence. Quality of life and survival could be improved by this method. Further trials are urgently warranted.

Table 1: MST of patients with WHO°III & IV gliomas (Kaplan-Meier-Estimation)		
MST from	**AA ; N = 53 pts months±se [95%CI]**	**GM; N = 126 pts months±se [95%CI]**
Newly diagnosed	**38.2±3.5 [31.3;45.0]**	**20.3±1.7 [17.0;23.6]**
1. LRF-DHT	**10.6±2.0 [6.7;14.4]**	**7.6±0.9 [5.9;9.3]**
Events/Censored N (%)	39/14 (26.4%)	101/25 (19.8%)

From newly diagnosed	1 yr .	2 yrs	3 yrs	4 yrs	5 yrs
AA WHO•III; N=53	**96**	**72**	**53**	**35**	**30**
GM WHO•IV; N=126	**82**	**41**	**23**	**11**	**11**

Survival probability (Kaplan-Meier-Estimation)

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