

| Tumor-Entität | Strahlentherapie | Chemotherapie | OR*, [%] nur herkömmliche Therapie | OR*, [%] mit Hyperthermie (OR = Overall Response) | Anzahl Patienten | Literatur- verweis |
|-------------------------------------|------------------|---------------|--|---|---------------------|-----------------------|
| Kopf- und Halskarzinom | ja | nein | - | 92 | 27 | [1] |
| Kopf und Hals | ja | nein | 58 | 74 | 65 | [2] |
| Kopf und Hals (Lymphknoten) | ja | nein | 41 | 83 | 41 | [3] [4] |
| Kopf und Hals | ja | nein | - | 97 | 76 | [5] |
| Kopf und Hals | ja | ja | - | 100 | 23 | [6] |
| Zervixkarzinom | ja | nein | 46 | 66 | 65 | [7] |
| Zervixkarzinom | ja | nein | 35 | 72 | 66 | [8] |
| Zervixkarzinom | ja | nein | 52,6 | 83,3 | 37 | [9] |
| Zervixkarzinom | ja | nein | 50 | 80 | 40 | [10] |
| Zervixkarzinom | ja | nein | 50 | 85 | 40 | [11] |
| Vulva/Vagina | nein | ja | 19 | 59 | 65 | [12] |
| Brustkarzinom (oberfl.) | - | nein | 41 | 61 | 148 | [13] |
| Brust-Adenokarzinom | ja | nein | - | 100 | 9 | [14] |
| Brustkarzinom | ja | nein | 35 | 62 | 306 | [15] |
| Brust (lokal fortschritten, primär) | ja | nein | 55 | 91 | 11 | [16] |

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|--|------------------|---------------|--|---|---------------------|-----------------------|
| Brust (rezidivierend nach Operation) | ja | nein | 89 | 83 | 6 | [16] |
| Brust (rezidivierend nach Strahlenth.) | ja | nein | 84 | 92 | 13 | [16] |
| Brust (rezidivierend) | ja | ja | - | 80 | 25 | [17] |
| Brust (rezidivierend) | ja | nein | 41 | 69 | 154 | [18] |
| Brust (fortgeschritten) | ja | nein | 63 | 83 | 24 | [19] |
| Magenkrebs | ja | - | 35,5 | 57,6 | 293 | [20] |
| Magenkrebs (fortgeschritten) | nein | ja | - | 39 | 33 | [21] |
| Magenkrebs (fortgeschritten) | ja | ja | - | 82 | 21 | [22] |
| Ösophaguskarzinom | nein | ja | 19 | 41 | 40 | [23] |
| Ösophaguskarzinom | - | - | 24,2 | 50,4 | 66 | [24] |
| Ösophaguskarzinom | ja | nein | 8 | 70 | 53 | [25] |
| Ösophaguskarzinom | ja | ja | 8 | 27 | 53 | [26] |
| Ösophaguskarzinom | ja | nein | 25 | 63 | 313 | [27] |
| Ösophaguskarzinom | ja | - | 59 | 81,2 | 66 | [28] |
| Magenkarzinom | nein | ja | - | 39 | 33 | [29] |

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|---------------------------|------------------|---------------|--|---|---------------------|-----------------------|
| Hepatozelluläres Karzinom | nein | ja | 43 | 56 | 48 | [30] |
| Kolorektales Karzinom | ja | nein | 10 | 43 | 24 | [31] |
| Blasenkarzinom | nein | ja | 22 | 66 | 52 | [32] |
| Blasenkarzinom | nein | ja | 22 | 66 | 52 | [33] |
| Rektumkarzinom | ja | nein | 0 | 11 | 48 | [34] |
| Rektumkarzinom | ja | nein | 33 | 69 | 117 | [35] |
| Rektumkarzinom | ja | nein | 55 | 71 | 101 | [36] |
| Rektumkarzinom | ja | nein | 5 | 23 | 122 | [37] |
| Oberflächenkarzinom | ja | nein | - | 100 | 22 | [38] |
| Oberflächenkarzinome | ja | nein | 62,6 | 82,8 | 92 | [39] |
| Subcutane Karzinome | ja | nein | 59 | 83 | 780 | [40] |
| Oberflächentumore | ja | nein | 25 | 46 | 85 | [41] |
| Oberflächentumore | ja | nein | 63 | 88 | 16 | [42] |
| Malignes Melanom | ja | - | 28 | 46 | 70 | [43] |

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|------------------------------------|------------------|---------------|--|---|---------------------|-----------------------|
| Malignes Melanom | ja | nein | 39 | 72 | 238 | [44] |
| Lungenkarzinom; (Wholebody HT) | nein | ja | 36 | 68 | 44 | [45] |
| Lungenkarzinom (nicht kleinzellig) | ja | nein | 20 | 73 | 49 | [46] |
| Lungenkarzinom (nicht kleinzellig) | ja | nein | - | 100 | 13 | [47] |
| Weichteilsarkom | ja | nein | - | 74 | 31 | [48] |
| Weichteilsarkom | ja | ja | - | 84 | 19 | [49] |
| Pankreas | ja | ja | 47 | 68 | 56 | [50] |
| Pankreas | nein | ja | 14 | 57 | 14 | [51] |
| Glioblastoma multiforme | ja | nein | 15 | 31 | 112 | [52] |

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HIRNTUMORE:

- A phase II clinical study on relapsed malignant gliomas treated with electro-hyperthermia. Fiorentini G, et al.
 - Prospective phase II trial for recurrent high-grade gliomas with low radiofrequency (LRF) hyperthermia
E. D. Hager, H. Sahinbas, D. H. Groenemeyer,
 - (Hager ED et al., *ASCO* 2003,#470; Sahinbas H. et al., *ASCO* 2008, #2047).
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ANDERE TUMORENTITÄTEN:

- In 2000 'THE LANCET' reported the results of a 358 patient Phase III clinical trial involving locally advanced pelvic tumors that was conducted by van der Zee, Gonzalez Gonzalez, van Rhooon, Dijk, van Putten and Hart and the Dutch Hyperthermia Group at University Hospital-Daniel den Hoed Cancer Center, Rotterdam and Academic Medical Center, Amsterdam, The Netherlands. The study reported that hyperthermia in combination with ionizing radiation improved complete response rates for bladder cancer from 51% to 73%, complete response rates for advanced cervical cancer from 57% to 83%, and overall three-year survival from 27% to 51%. (See Vol. 355, pp. 1119-1125.)
- In 1996 the International Journal of Radiation Oncology, Biology, Physics reported the results of a **306 patient Phase III clinical trial** involving superficial localized **breast cancer** conducted by Vernon, Hand, Field, Machin, Whaley, van der Zee, van Putten, van Rhooon, van Dijk and Gonzalez Gonzalez at Hammersmith Hospital, London and MRC Cancer Trials Officer, Cambridge, United Kingdom, Daniel den Hoed Cancer Center, Rotterdam and Academic Medical Center, Amsterdam, The Netherlands and Prince Margaret Hospital, University of Toronto, Canada. The study concluded that the addition of hyperthermia to ionizing radiation increased complete response from 41% to 59% and local **relapse-free survival from 30% to 50%**. (See Vol. 35, No. 4, pp. 731-744.)
- In 1996 the International Journal of the American Cancer Society, **CANCER**, reported the results of a 23 patient clinical trial involving carcinoma of the **head and neck region**, carcinoma of the breast and malignant melanoma, conducted by Lee, Mayer and Hallinan of Johns Hopkins Hospital. The study produced complete response in 89% of patients and partial response in 11% of patients, with a two-year actuarial local control rate of 74% using interstitial hyperthermia in combination with radioactive seeds (brachytherapy). The study concluded that "outpatient interstitial thermoradiotherapy is convenient, safe, and efficacious for treating human neoplasms". (77/11, pp. 2363-2370.)
- Breast Jones et al. (J. of Clin.Oncology Vol.23.;13, 2005)
109 Patients with **breast CA** close to skinsurface compr. response rate of 68,1 % (radiation + HT) vs. 42,3% (radiation alone)
most significant difference with patients previously radiated :
68,2% in radiation+ HT vs. 23,5 % radiation alone
- Phase III trials: **Cervix CA** van der Zee/ Franckena et al (ESHO 2007)
12 years survival; 58 pat. (Rad.+HT) vs. 56 pat. (Rad. alone)
better lokal Control: 36 % (radiation alone) vs. 56 % (radiation + HT)
ov. Survival >12 years: 20 % (radiation alone) vs. 37 % (radiation + HT) at p=0,02
- **Soft Tissue Sarcoma Phase III Study** (Issels et al ASCO 2007) Journal of Clinical Oncology, 2007 ASCO Annual Meeting Proceedings Part I. Vol 25, No. 18S (June 20 Supplement), 2007: 10009
340 patients. (locally advanced = 5 cm grade II / III)
Neoadjuvante Chemotherapie combined with hyperthermia in one of the arms.
Results: 2 years locally progression free survivalrate
chemo + HT : 84 % vs 57 % chemo(p<0,02).

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- Studie: R. Issels, GFS-Forschungszentrum für Umwelt und Gesundheit, Institut für Molekulare Immunologie und Klinikum Großhadern, Medizinische Klinik III: „Hyperthermia Combined with Chemotherapy-Biological Rationale, Clinical Application and treatment Results“ Onkologie 1999;22:374-381
 - Weiterhin berichten Issels et al. Sowie van de zee et al. über überzeugende Ergebnisse in der Behandlung von Tumoren die refraktär gegen eine Operation, Chemotherapie und Radiotherapie waren. Bei Patienten, die mit der Kombination aus regionaler Hyperthermie plus Chemotherapie behandelt wurden, erreichte er eine Remissionsrate von 37%. In einem neoadjuvanten Ansatz mit der Kombination aus regionaler Hyperthermie plus EIA (Etoposid, Ifosfamid, Adriamycin) betrug die Remissionsrate 47 %. Die 5-Jahresüberlebensrate lag bei 46%.
 - Kakehi et al. behandelten Patienten mit Magenkarzinom und Patienten mit Pankreaskarzinom mit einer regionalen Hyperthermie von in Kombination mit einer Chemotherapie bestehend. Die Remissionsraten betragen 39% bzw. 36%, und bei 2/3 der Patienten konnte auch eine Besserung der tumorbedingten Symptomatik erreicht werden .
 - Van de Zee J, Gonzáles DG, van Rhoon GC, van Dijk JDP, van Putten WLJ, Hart AAM. Comparison of Radiotherapy alone with Radiotherapy plus Hyperthermia in Locally Advanced Pelvic Tumours: a Prospective, Randomised, multicentre trial. The Lancet 2000;355:1119-1125. Konnte in dieser Phase III-Studie ebenfalls eine deutliche Überlegenheit der Kombinierten Therapie mit Hyperthermie nachweisen. So das diese Therapiekombination in Holland bei bestimmten Tumorerkrankungen und Lokalisationen als Standardtherapie eingesetzt werden.
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Hyperthermie & Strahlentherapie

Brustkrebs (Jones et al 2007 + 2005)

randomisierte Phase III und Phase I Studien

109 Patienten bei oberflächennahem Brustkrebs

umfassenden Ansprechrates von 68,1 % (STH + HT)

vs. 42,3% (STH allein)

Deutlichster Abstand bei Patienten die zuvor schon

strahlenbehandelt wurden: 68,2% im Arm STH + HT

vs. 23,5 % bei STH allein

(Jones et al., Journal of Clinical Oncology Vol. 23, No 13, May 1, 2005.)

In einer Erweiterung mit thermisch sensitiven Liposomen als Träger von Doxorubicin als Phase I Studie kommen die Autoren zum bislang vorsichtigen Schluss, dass auch hier die Hyperthermie mit einer liposomalen-thermosensitiven Chemotherapie die „Anti-Tumor-Effekte“ verstärkt. *(Jones et al, June 2007, 24th Annual Meeting of ESHO, Prag, Abstracts S. 11)*