Purpose
Following the discovery of tumor-specific frequencies in patients with advanced cancer, compassionate
treatment with tumor-specific frequencies administered at levels that are significantly below the levels
generated by cell phone will be offered to patients with limited therapeutic options.

<table>
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<th>Condition</th>
<th>Intervention</th>
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<tbody>
<tr>
<td>Cancer</td>
<td>Device: Intrabuccally-administered amplitude-modulated RFEM</td>
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Study Type: Expanded Access

Official Title: Compassionate Treatment of Advanced Cancer With Amplitude-Modulated Electromagnetic Fields

Resource links provided by NLM:

MedlinePlus related topics: Cancer Electromagnetic Fields
U.S. FDA Resources

Further study details as provided by Pasche, Boris, M.D.:

Intervention Details:
Device: Intrabuccally-administered amplitude-modulated RFEM

Generation of amplitude-modulated electromagnetic fields: the device consists of a battery-driven radiofrequency (RF) electromagnetic field generator connected to a 1.5 meter long 50 Ohm coaxial cable, to the other end of which a spoon-shaped mouthpiece made of steel is connected with the inner conductor. The RF source of the device corresponds to a high-level amplitude-modulated class C amplifier operating at 27.12 MHz. The modulation frequency can be varied between 0.01 Hz and 150 kHz with a modulation depth of 85 ± 5%. The RF output is adjusted to 100 mW into a 50 Ohm load using a sinusoidal modulated test signal, which results in an emitting power identical to that of the device used in the treatment of insomnia (Pasche et al 1996, 19:327-336).

Detailed Description:

We have previously shown that the intrabuccal administration of low and safe levels of electromagnetic fields, amplitude-modulated at a frequency of 42.7 Hz by means of a battery-powered portable device modifies the electroencephalographic activity of healthy subjects (1, 2) and is associated with subjective and objective relaxation effects (3). These results prompted us to study the effects of the 42.7 Hz frequency in patients suffering from insomnia. A randomized control trial did not reveal any difference between 42.7 Hz treatment and placebo (4) but sequential administration of four insomnia-
specific frequencies, including 42.7 Hz, resulted in a significant decrease in sleep latency and a
significant increase in total sleep time in patients suffering from chronic insomnia (5). Dosimetric
studies have shown that the amount of electromagnetic fields delivered to the brain of patients with this
approach is 100 to 1000 times lower than the amount of electromagnetic fields delivered by handheld
cellular phones and do not result in any heating effect within the brain (4). The U.S. FDA has
determined that such a device is not a significant risk device. Lastly, a long-term follow-up survey of
807 patients who have received this therapy revealed that the rate of adverse reactions were low and
were not associated with increases in the incidence of malignancy or coronary heart disease (6).

Given the advantageous safety profile of athermal, non-ionizing radiofrequency electromagnetic fields
and the emerging evidence that low levels of electromagnetic or electric fields may modify the growth
of tumor cells (7-9), we decided to test the hypothesis that low levels of electromagnetic fields
modulated at tumor-specific frequencies may alter the growth of human malignancies. We have
developed a novel patient-based biofeedback method with the goal to identify cancer-specific
frequencies and have examined patients with this approach. Following identification of such
frequencies in a total of 163 patients, we will offer compassionate treatment to 28 patients with
advanced cancer and limited palliative therapeutic options.

Eligibility

Ages Eligible for Study: 18 Years to 90 Years
Genders Eligible for Study: Both

Inclusion Criteria:
• Diagnosis of cancer with advanced disease and limited therapeutic options

Exclusion Criteria:
• Any patient with curative treatment options

Publications:
Kelly TL, Kripke DF, Hayduk R, Ryman D, Pasche B, Barbault A. Bright light and LEET effects on
Pasche B, Erman M, Hayduk R, Mitler MM, Reite M, Higgs L, Kuster N, Rossel C, Dafni U, Amato D,
Barbault A, Lebet JP. Effects of low energy emission therapy in chronic psychophysiological insomnia.
Electroencephalographic changes following low energy emission therapy. Ann Biomed Eng. 1996
Amato D, Pasche B. An evaluation of the safety of low energy emission therapy. Compr Ther.
Additional publications automatically indexed to this study by National Clinical Trials Identifier (NCT ID):

Responsible Party: Cabinet Avenue de la gare 6, CH-1003-Lausanne (Boris Pasche)
Study ID Numbers: ADLG3
Study First Received: December 5, 2008
Last Updated: December 6, 2008
ClinicalTrials.gov Identifier: NCT00805337  History of Changes
Health Authority: Switzerland: Laws and standards

Keywords provided by Pasche, Boris, M.D.:
Cancer amplitude-modulated electromagnetic fields

ClinicalTrials.gov processed this record on June 30, 2009