



others

## **The development of drugs for neutron capture therapy - from idea to implementation: physical, pharmacological, radiobiological, regulatory aspects**

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Being a binary therapeutic modality, the efficacy of Neutron Capture Therapy (NCT) is highly dependent on the ability of the used for the therapy a carrier-drug to deliver required amount of neutron capture agent (boron, gadolinium, lithium etc.) to tumor [1]. Thus, availability of such carriers as approved drugs for clinical application is crucial for successful implementation and use of NCT in curing cancer. <sup>10</sup>B is not the only isotope that can be used in NCT. Other isotopes like <sup>157</sup>Gd and <sup>6</sup>Li can also be considered as neutron capture agents for NCT [2,3]. Every isotope has its advantages and disadvantages and only the properties of its pharmaceutical dosage can be a merit of its suitability for NCT.

On the example of boron, the "boron dose" determines more than 80% of the total delivered absorbed dose during boron mediated NCT. Consequently, absorbed dose value prescriptions for a tumor and limitations for normal tissues together define requirement for any NCT drug. Acceptable T/N ratio is determined by radiosensitivity of corresponding tumor and normal tissues while minimum concentration of dose enhancing isotope is determined by neutron beam contamination with gamma and fast neutrons. T/N ratio and minimum concentration in tumor are independent parameters and a potential drug should match both of them.

Before any substance is allowed to be administered to a human patient it should become a biocompatible pharmaceutical preparation with necessary for NCT characteristics and pass through formalized preclinical and clinical studies. Most of the substances are rejected on the stage of preclinical studies. Preclinical studies are dedicated to prove safety and efficacy of the drug for human patients, basing on the results of the studies in laboratory animals. Not every research, which was made in laboratory animals can be considered as preclinical but only that which were performed in concordance with national preclinical recommendations.

References:

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