

Advanced Radio-guided Surgery: Tc-99m-labelled Nanoparticles for the Detection of Sentinel Lymph Nodes

Reference No: B82027

CHALLENGE

In case of breast cancer, malignant melanoma and many other types of cancer, the removal and histological examination of the first lymph nodes in the lymphatic drainage area of the primary tumor, the so-called sentinel lymph nodes (SLNs), is essential for precise diagnosis of the disease and correct choice of therapy. Biopsy limited to SLNs is used to determine whether tumor cells are already present in these first lymph nodes, which in turn provides information about the metastatic stage of the tumor in the least invasive way possible. The SLNs are localized and removed during surgery. For this, a radiopharmaceutical – a radiolabeled colloidal particle or radiolabeled macromolecule – is injected into the vicinity of the tumor, which then drains into the SLNs and is detected using a hand-held gamma probe.

Currently various radiotracers labeled with technetium-99m (^{99m}Tc) are used for SLN biopsy. However, each of them has disadvantages. For example, [^{99m}Tc]Tc-labeled nanocolloids prepared from human serum albumin are problematic due to their allergenic potential and their classification as a blood product, which implies time-consuming regulatory obligations such as extended patient information and batch documentation inspected by legal authorities. Furthermore, the market already had to experience that the supply was not continuously ensured. [^{99m}Tc]Tc-sulfur colloids (SCs) show a wide size distribution with many large particles, making them not ideal for SLN detection as they remain largely at the injection site. Therefore, the [^{99m}Tc]Tc-SCs are filtered after labelling to obtain the appropriate size and size distribution, but this in turn leads to a significant loss of radioactive label. Finally, [^{99m}Tc]Tc-tilmanocept as another competitor is a comparably expensive radiotracer.



INNOVATION

The radiopharmaceutical presented here for detection of sentinel lymph nodes has the following properties: 1) rapid clearance from injection site, 2) selective uptake into the lymphatic system and high retention in sentinel lymph nodes, 3) no classification as blood product 4) low uptake in downstream lymph nodes, 5) easily detectable signal intensity and 6) biodegradation/elimination after signal detection.

COMMERCIAL OPPORTUNITIES

Cost effective SLN detection agent with superior characteristics for radioguided surgery. Since SLN scintigraphy already has to be performed internationally according to the oncology guidelines in about 30% of all patients with an initial diagnosis of breast carcinoma and at least 10% of all patients with malignant melanoma, this is an innovation with a huge worldwide market potential.

In addition, there are further fields of application due to the increasing use of the SLN method, e.g. for head-and-neck tumors, cervical carcinomas and prostate carcinomas.

DEVELOPMENT STATUS

In vitro proof of concept