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Trofimiuk-Muldner, Elwira Przybylik-Mazurek, prognosis, however a subgroup of patients develops progressive disease and complete remission. When Ct level elevated a localization of postsurgical remnant tissue surgery intervention tissues receptor expression in MTC and the best pharmacokinetics properties of compound among the clinical part of the trial. therapeutic amount Trial Design: No of patients: Main diagnosis: SAT 172

The ultimate goal of as a candidate for innovative therapy agents targeted at specific biological processes 111 r-type specific, precise and non-invasive localization of tumour 111s

MEN2A, after thyroidectomy due to MCT, basal calcitonin level: 279 pg/mL, Bone marrow estimate: 0.32 Gy/GBq, stomach dose – 0.13 Gy/GBq, and bone marrow dose – 0.013 Gy/GBq. (Fig.5).

During the first clinical phase of the trial, each patient received 2 different In-CP04 (200 M Ci) doses: a low, diagnostic of 10 µg and a high, therapeutic of 50 µg. Biodistribution and dosimetry data were assessed based on serial planar and SPECT/CT images. CONCLUSION

1) MTC metastases can be detected with 111In-CP04.

2) Biodistribution and dosimetry data make CP04 a promising radiopharmaceutical for MTC therapy if labeled with 111Lu.

3) At this stage of the Grant-T-MTC Study, the promising properties of the new radionuclide analogue in soluble and initial positive dosimetry calculations warrant further studies on the new gastrin analogue as candidate to the theranostic approach in the MTC management strategy. The confirmatory second part of clinical phase of trial has just been started.

Our study may be maybe that it is the first step in the development of a more efficient therapeutical strategy against MTC, with remains a challenging neoplasm.


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MATERIAL AND METHODS

Phase 1: according to the Study Protocol 4 patients were enrolled in the study. Basal calcitonin levels ranged between 279 and 824 pg/mL (normal range: 0 – 10 pg/mL).

• 3 patients with progressive/metastatic MEN-related MTC with positive 18F-FDG PET/CT/TI/MRI.

The results of our project conducted within an international collaboration, is to establish the safety of the iv. administration of therapeutic amounts of CP04 and to assess the biodistribution and dosimetry of In-CP04 in MTC and normal tissues. The proposed gastrin-analogue (DOTADP), Alula-Thr-Gly-Tyr-Met-Asp-Phe-His (CP04) has been chosen as a candidate for innovative therapy because of high CK-2 receptor expression in MTC and the lead pharmacokinetics properties of this compound among numerous tested gastrin analogues.

At present the principal part of the study has been finalized, and we obtained positive results with confirmed the possibility of applying In-CP04 in the MTC management strategy.

We herein present first promising results of the clinical part of the European project (Grants-T-MTC) and biodistribution of a Therapeutic amounts of the gastrin analogue, CP04 (DOTA(DP)-Ala-Thr-Gly-Tyr-Met-Asp-Phe-NH2) for potential future Pharmacokinetic management of MTC with [111In]LuCP04.

Clinical trial:

Trial Design: Phase I multi-center randomized clinical trial No of patients: minimum 25 patients Main diagnosis: Patients with progressive or metastatic MTC • Positive • Elevated calcitonin (CT) • or elevated calcitonin (CT) and/or positive calcitonin doubling time (DT).

Clinical Study period per patient: 1 month plus 4 months of follow-up.

RESULTS

No side effects were observed during injection of either CP04 dose. In all patients In-CP04 uptake was confirmed in MTC lesions regardless of peptide dose. Only in one patient the uptake was weak for the therapeutic amount of peptide dose. Only in one patient the uptake was weak for the therapeutic amount of peptide dose. Only in one patient the uptake was weak for the therapeutic amount of peptide dose.

Clearance curves for both doses were similar with little variation across patients. Dose limiting organ were kidneys. Effective radiation doses were 4.9 mSv/200 MBq and 5.8 mSv/200 MBq, for 10 and 50 of In-CP04, respectively. Estimated kidney, stomach and bone marrow dose are 0.013 Gy/GBq. (Fig.5).

• 2 patients with sporadic MTC, basal calcitonin level: 563 pg/mL.

• Phase 1B: If NO severe adverse event occur.

• Phase 1A: if NO severe adverse event occur.

Figure 1. A 56-year old female patient with MEN2A, after thyroidectomy due to MCT, basal calcitonin level: 478 pg/mL, due to MCT and after bilateral adrenalectomy due to phaeochromocytoma, basal calcitonin level: 563 pg/mL

Figure 2. A 56-year old female, MEN2B, after thyreoidectomy due to MTC, basal calcitonin level: 478 pg/mL. Figure 3. 3.46-year old female, MEN2B, after thyreoidectomy due to MTC and adrenalectomy due to phaeochromocytoma, basal calcitonin level: 563 pg/mL

Figure 4. 46-year old male with sporadic MTC, basal calcitonin level: 478 pg/mL, short calcitonin doubling time, no tumour tissue was detected by available imaging pathologies.

Fig. 1

Fig. 2

Fig. 3

Fig. 4

Fig. 5

The authors have nothing to disclose.

SOURCES OF SUPPORT

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Figure 6. Dose limiting organs were kidneys. Effective radiation doses were 4.9 mSv/200 MBq and 5.8 mSv/200 MBq, for 10 and 50 of In-CP04, respectively. Estimated kidney, stomach and bone marrow dose are presented on the right graph.