The biodistribution of Miltuximab® using Gallium-67 nuclear imaging: The MILGa-01 First in Human Trial

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Background: Miltuximab® is a chimeric antibody targeting Glypican-1 which is overexpressed in prostate cancer. This Phase I trial uses a single dose (250 MBq, 1mg) of Miltuximab® conjugated with the chelator (DOTA) radiolabelled with ^{67}Ga (Gallium-67) with aims to establish dose safety and tolerability.

Methods: Metastatic patients were dosed with unlabelled Miltuximab® conjugated with DOTA followed by the infusion of ^{67}Ga-Miltuximab® an hour after. Patients underwent whole body γ-camera scans and SPECT/CT scans up to 144 hours post-infusion. Standard of care imaging was performed at least 14 days before and after participation. Between cohorts, safety was evaluated by an external monitoring committee.

Results: Twelve patients were enrolled into the trial. Miltuximab® was well tolerated and did not elicit any drug-related adverse reactions. 30 minutes post-^{67}Ga-Miltuximab® dose, intense mediastinal uptake was observed, followed by liver and spleen uptake from 30 minutes to 72 hours post dose. Pre-infusion of unlabelled Miltuximab® resulted in reduced liver accumulation and increased distribution in the rest of the body.

Conclusions: This study is the first in human for Miltuximab® and demonstrates its potential for further clinical evaluation as a theranostic in prostate cancers.

Conflict of interest:
None of the authors have any potential conflicts to disclose.

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