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Feasibility of Administering Anti-CD45 Iodine (^{131}I) Apamistamab [Iomab-B] for Targeted Conditioning in Older Patients with Active, Relapsed or Refractory AML without Lead-Lined Rooms: Ongoing Phase III SIERRA Trial Experience at 6 Study Sites

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2. Memorial Sloan Kettering Cancer Center, New York, NY
3. Medical College of Wisconsin, Milwaukee, WI
4. Weill Cornell Medical Center, New York, NY
5. University of Nebraska Medical Center, Omaha, NE
6. Stony Brook University Hospital, Stony Brook, NY
7. Actinium Pharmaceuticals, New York, NY
8. Versant Physics, Kalamazoo, MI

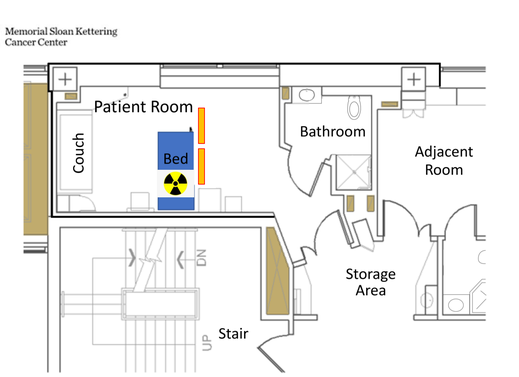
Introduction

Patients ≥55 years of age with active, relapsed or refractory acute myeloid leukemia (R/R AML) who have failed standard induction and salvage therapies do not routinely undergo allogeneic hematopoietic cell transplantation (HCT) due to their inability to receive myeloablative conditioning. The SIERRA trial is a prospective, randomized, phase 3, open-label, multicenter trial designed to address this significant unmet need. Preliminary results have shown that targeted conditioning with Iomab-B can lead to successful engraftment.

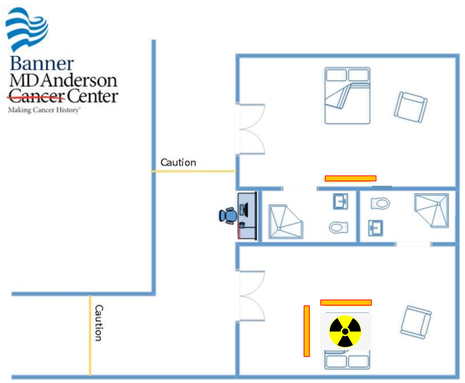
Due to the activity level of infused ^{131}I (300-1030 mCi, median ~600 mCi), patients are shielded from the public in a hospital room for 3-7 days. As a dedicated lead-lined isolation room is not always available, we present our experience from 6 SIERRA study sites demonstrating the feasibility of using mobile shielding in standard inpatient rooms to comply with radiation safety regulations.

Method

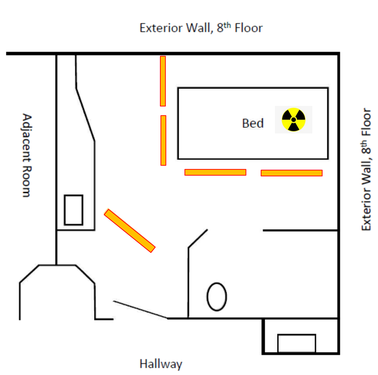
Six hospitals (Memorial Sloan Kettering Cancer Center, Banner MD Anderson Cancer Center, Medical College of Wisconsin, Weill Cornell Medical Center, University of Nebraska Medical Center, and Stony Brook University Hospital) out of 20 sites have identified regular corner inpatient rooms (4 of them are on top floor) for isolation after Iomab-B therapeutic infusion. Shielding calculations were performed taking into consideration the patient room layout, bed position, surrounding areas (hallway, satellite nursing station and adjacent rooms) and their occupancy to determine placement of mobile shielding. Radiation surveys were performed in identified areas following Iomab-B infusion and during the isolation period.



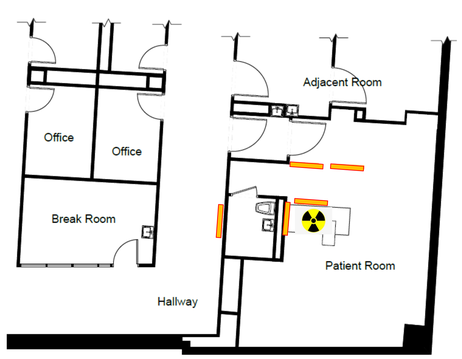
a. Memorial Sloan Kettering Cancer Center



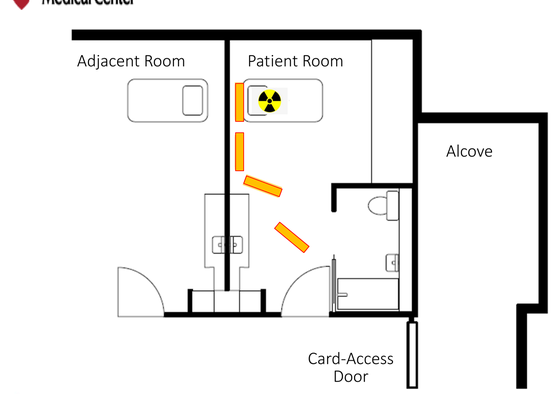
b. Banner MD Anderson Cancer Center



c. Medical College of Wisconsin



d. Weill Cornell Medical Center



e. University of Nebraska Medical Center

f. Stony Brook University Hospital

Figure 1. Floor plans (a-e) or room photo (f) and shielding placement from 6 study sites

Mobile shields **Patient bed location**

Results

Both pre-isolation calculations with ^{131}I and surveys immediately following the therapeutic dose of Iomab-B (time of maximum exposure) have shown that appropriate use of mobile shields can effectively decrease the exposure rate in surrounding public accessible areas to be less than the regulated limit of 2 mR/hour.

Table 1. Shielding arrangement, room selection, evaluation methods, and survey results

Hospitals	Shielding placement and number of shields	Room		Available Evaluations	Survey results (mR/hr) immediately after infusion		
		Corner room	Top floor		Outside of room	Adjacent room or nursing station	Room above/below
Memorial Sloan Kettering Cancer Center	Bed (2) Satellite nursing station (1)	Y	N	10 patients 543-1030 mCi	0.01-1.95	0.2-1.82	0.5-1.88
Banner MD Anderson Cancer Center	Bed (2), Adjacent room (1)	Y	Y	7 patients 424-960 mCi	0.6-2.2*	0.11-1.48	0.18-0.66
Medical College of Wisconsin	Bed (4), Satellite nursing station (1)	Y	Y	2 patients 529-893 mCi	0.6	0.34-0.75	-
Weill Cornell Medical Center	Bed (2), Anteroom room (2) Hallway (1)	Y	N	1 patient 770 mCi	0.24-0.45	0.26	0.17
University of Nebraska Medical Center	Bed (1), Adjacent room (2), Entrance (1)	Y	Y	Calculation with 800 mCi	0.23-0.5	-	0.5
Stony Brook University Hospital	Bed (2) Satellite nursing station (2) Entrance (1)	Y	Y	1 patient 702 mCi	0.34-1.7	0.56	-

* Hallway outside of patient room, restricted access until below 2 mR/hr.

Conclusions

Based on the experience from 6 active study sites, including the two highest enrolled sites, it is concluded that lead-lined rooms are not required for treating R/R AML patients with Iomab-B. The use of mobile shields enables treatment of patients in regular inpatient rooms.