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Cutting-edge Science at
Europe's largest Urology Congress

^{89}Zirconium-labelled girentuximab (^{89}Zr-TLX250) PET in Urothelial Cancer Patients (ZiPUP) – A phase I trial of a novel staging modality for urothelial carcinoma

Dickon Hayne, Richard Gauci, Pravin Viswambaram, Teng Hoo, Kevin G Keane, Steve P McCombie, Samantha R Oakes, Elizabeth Liow, Jayne Lim, Cynthia Hawks, Nat Lenzo, Thomas Ferguson, Katie Meehan, Andrew Redfern

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Conflict of Interest Disclosure

- I have the following potential conflicts of interest to report

Advisory Boards

Urogen
BMS
Pacific Edge
AstraZeneca

Travel / Meeting Support

AstraZeneca
Telix Pharmaceuticals
BJUI
ANZUP

Research Funding / Support

Telix
AstraZeneca
Valar Labs

Speaker Meetings

BMS
GSK

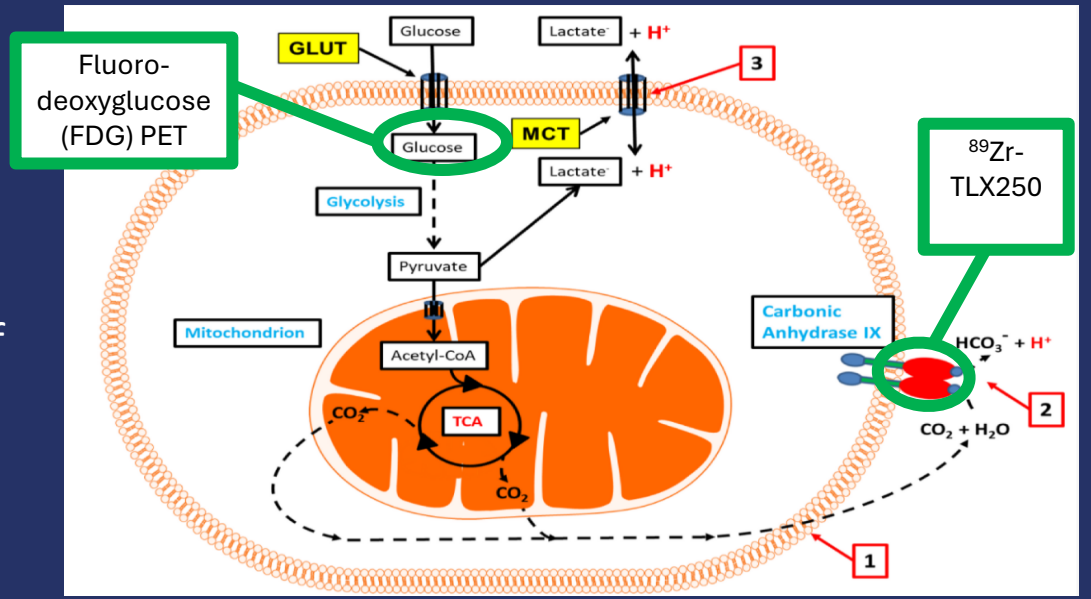
The Targets

Need better staging for UC

- CT has low sensitivity for detecting oligo-metastatic disease
- FDG PET limited by renal excretion.

89Zr -girentuximab PET not previously been investigated in UC

- Girentuximab is a CA-9 ligand expressed on renal and UC
- 89Zr-TLX250 metabolized hepatically with minimal renal excretion
- 89Zr-TLX250 has utility in RCC staging & may have utility staging of urothelial cancer, with less renal excretion as compared to FDG



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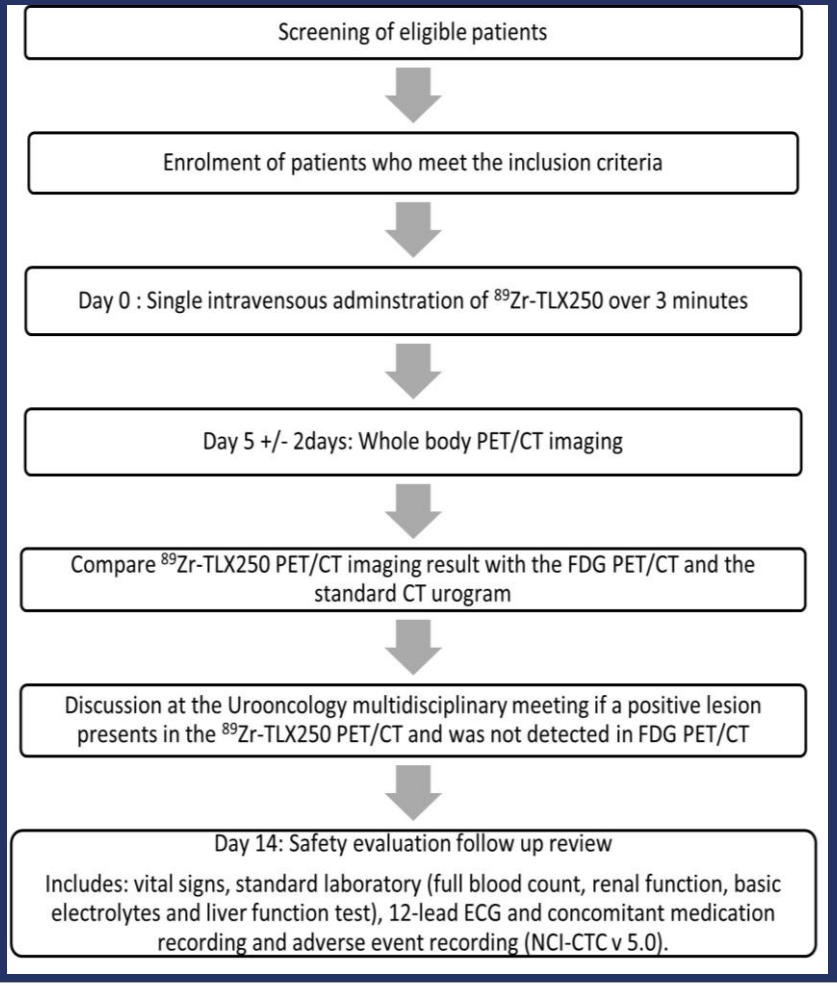
Study Design and Methods

- ZipUP is a prospective, open-label, single-centre study
- **Participants**
  - 20 patients being staged with FDG PET
    - 13 pts -Pre-cystectomy or Neph-U
    - 7 with known metastatic disease
- Single dose of intravenous ^{89}Zr-girentuximab (37 MBq)
- Imaging 5±2 days later. (ZipUp PET)

- **Primary objective**:
  - Feasibility
- **Secondary objectives**:
  - Effectiveness detecting primary and metastatic disease
  - Sensitivity and specificity for lymph node (LN) & metastasis detection compared to FDG PET.

Study schema



Results - Demographics

	Non-metastatic	Metastatic	Overall
Number	13	7	20
Gender	M = 8 / F = 5	M = 5 / F = 2	M = 13 / F = 7
Mean age	69.2	71	69.9
Mean BMI	27.0	26.5	26.9
Median ECOG	0	0	0
Primary bladder	11	3	14
Primary UTUC	2	4	6

Results

- ZipUp PET was feasible and safe and tolerable
  - 15 AEs & 1 SAE
  - None attributed to tracer administration
- FDG and ZipUp **congruent** in 17/20 cases.
- Metastatic sites imaged:
  - **12** on FDG vs **8** on ZipUp
- Mean tumour-to-mediastinum SUVmax ratio:
  - **Higher for FDG** vs ZipUp (5.10 [2.4] vs 1.79 [1.3]).
- 11 surgical pts with LND for pathologic concordance
  - **Higher for ZipUp** vs FDG (72.7% vs 63.6%)
- Detection rates for primary bladder lesions:
  - **Same** (50% (4/8) for both tracers)
- Detection rates or upper tract UC
  - **Higher for FDG** vs ZipUp (4/7 vs 3/7)

Conclusions:

- ZipUp PET is feasible, safe & tolerable
- ZipUp PET has a lower SUVmax and may be less effective than FDG PET in detecting metastatic sites.
- Potential role of CAIX-targeting for novel diagnostic and therapeutic approaches for pts with UCs where disease concordant with FDG PET