

TYPE OF CANCER:

Renal Cell Carcinoma

TYPE OF TRIAL:

Phase III

TRIAL SPONSOR:

Wilex

PRINCIPAL INVESTIGATOR:

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STUDY SUMMARY

A Comparative Study of PET/CT vs. Diagnostic CT for the Detection of Clear Cell Renal Cell Carcinoma in Pre-surgical Patients with Renal Masses Using Iodine-124 labelled Chimeric G250 (124IcG250)

PRETREATMENT ASSESMENT

- Informed consent
- Medical history
- Physical Examination
- Vital signs
- Serum pregnancy test
- 12-lead ECG
- Hematology
- Serum chemistry
- Urinalysis
- Coagulation
- HACA serum sample
- Concomitant medications
- Recording of adverse events

ENTRANCE CRITERIA FOR PARTICIPATION IN TRIAL

Inclusion Criteria

Patients will be eligible for enrolment if they fulfill the following criteria:

1. Subject is over 18 years of age.
2. Presence of a renal mass.
3. Scheduled for surgical resection of renal mass (partial or total nephrectomy, open or laparoscopic technique).
4. Expected survival of at least 3 months.
5. ECOG < 2.
6. The following laboratory results should be within the following limits within the last 2 weeks prior to study day 1:
 - Absolute neutrophil count (ANC) $\geq 1.5 \times 10^9/L$
 - Platelet count $\geq 100 \times 10^9/L$
 - Serum bilirubin $\leq 2.0 \text{ mg/dL}$

- Aspartate aminotransaminase (AST) $\leq 2.5 \times \text{ULN}$
 - Alanine aminotransferase (ALT) $\leq 2.5 \times \text{ULN}$
 - Serum creatinine $\leq 2.0 \text{ mg/dL}$ (calculated creatinine clearance $>45 \text{ ml/min}$)
7. Negative serum pregnancy test; to be performed on female patients of childbearing potential within 24 hours prior to receiving investigational product. All females of childbearing potential must indicate intent to avoid pregnancy and must use an accepted, effective method of contraception for the duration of the study.
8. Recovered from toxicity of any prior therapy.
9. Able and willing to give valid written informed consent

Exclusion Criteria

Patients will be excluded from the study if they fulfill any of the following criteria:

1. Metastasis of primary tumor other than RCC.
2. Prior history of malignancy within the last 5 years.
3. Prior exposure to murine proteins or chimeric antibodies.
4. Intercurrent medical condition that may limit the amount of antibody to be administered.
5. Intercurrent medical condition that renders the patient ineligible for surgery.
6. New York Heart Association Class III/IV cardiac disease.
7. History of autoimmune hepatitis.
8. Chemotherapy, radiotherapy, or immunotherapy within 4 weeks prior to $^{124}\text{IcG250}$ infusion on day 1.
9. Mental impairment that may compromise the ability to give informed consent and comply with the requirements of the study.
10. Lack of availability for immunological and clinical follow-up assessments.
11. Participation in any other clinical trial involving another investigational product within 4 weeks prior to enrolment.
12. Women who are pregnant or breastfeeding.
13. Allergy to iodine, hyperthyroidism, or Grave's Disease.
14. Known allergic reaction to human serum albumin.
15. Contraindication for contrast-enhanced CT or PET/CT.
16. Contraindication to potassium iodide intake (see package insert).