Informed Consent Form

Study Title:
Evaluation of Dual-Targeted ^{68}Ga-FAPI-PSMA PET/CT for the Diagnosis and Staging of Solid Tumors

Version Number: Ver 3.0, January 17, 2026

Last Approved： March 24，2026

Study Institution: [Anonymized]

Principal Investigator: [Anonymized]

Participant Name:
Participant Initials:
Address:
Telephone:

Dear Sir/Madam,

You are being invited to participate in a clinical study. This informed consent form provides you with information to help you decide whether to participate in this study. Please take sufficient time to read the following content carefully. If there are any terms or information you do not understand, please discuss them with the study physician.

Your participation in this study is entirely voluntary. This study has been reviewed and approved by the Ethics Committee.

1. Background

Prostate cancer is the second most common cancer among men worldwide, with nearly 1.3 million new cases annually, accounting for 13.5% of newly diagnosed cancers. In recent years, the incidence in China has increased rapidly. In 2016, there were approximately 120,000 new cases, ranking fifth among male malignancies and becoming the most common tumor of the male genitourinary system. It is expected that both incidence and mortality will continue to rise, reaching 237,000 new cases by 2030.

The higher mortality rate in China compared to Western countries is mainly due to the lack of effective diagnostic and treatment guidance methods. Early diagnosis and early treatment are critical to prolong survival and reduce mortality. Therefore, accurate early diagnosis, clinical staging, and treatment guidance are essential for improving prognosis.

In the era of precision medicine, surgical resection based on early diagnosis remains the optimal treatment. Current imaging techniques such as biopsy, PSA testing, CT, MRI, and PET/CT play important roles in lesion evaluation. However, due to spatiotemporal discrepancies and differences between preoperative imaging and intraoperative anatomy, surgeons still rely heavily on experience, palpation, and visual inspection. This may lead to missed small lesions, contributing to postoperative recurrence.

Similarly, ovarian cancer and endometrial cancer are major threats to women's health. Endometrial cancer has the highest incidence but relatively favorable prognosis, often related to estrogen stimulation. Ovarian cancer, although less common, is highly lethal, with approximately 70% diagnosed at an advanced stage, leading to poor survival.

Liver cancer is also one of the most common malignancies worldwide and ranks as the second leading cause of cancer-related death in China. It is often diagnosed at an advanced stage due to its insidious onset. As with prostate cancer, intraoperative identification of tumor margins and small lesions remains a major challenge.

Prostate-specific membrane antigen (PSMA) possesses enzymatic functions (GCPII and FOLH1) and is highly overexpressed in nearly all prostate cancers, including high-grade, metastatic, and castration-resistant disease, while only minimally expressed in normal tissues. Therefore, PSMA is an ideal biomarker for sensitive and specific imaging.

Fibroblast activation protein (FAP) is a type II transmembrane glycoprotein highly expressed in cancer-associated fibroblasts (CAFs), which constitute up to 90% of tumor stroma in epithelial tumors. FAP is widely expressed across multiple tumors, including prostate cancer, liver cancer, ovarian cancer, and endometrial cancer.

Thus, the development of dual-target probes targeting both PSMA and FAP has significant research and clinical value for early detection and diagnosis of primary and metastatic lesions.

2. Study Objective

To compare the diagnostic performance of three imaging agents:
68Ga-FAPI-PSMA, 68Ga-PSMA-617, and 68Ga-FAPI-04

Specifically evaluating their effectiveness in:

- Tumor differentiation
- Staging
- Metastasis detection
- Early diagnosis

- Treatment monitoring
- Prognostic assessment

3. Study Procedures

A total of **20 participants** will be enrolled.

Each participant will receive:

- Intravenous injection of imaging tracers
- PET/CT scans within specified timeframes

The administered dose is approximately **0.1–0.15 mCi/kg**.

(1) Inclusion Criteria

Age 18–75 years, male, ECOG score 0 or 1

Patients who are scheduled for pathological biopsy or tumor surgery within the past 2 months, including suspected or confirmed solid tumors (prostate cancer, liver cancer, ovarian cancer, endometrial cancer, etc.)

Expected survival ≥12 weeks

Hematologic and organ function requirements: WBC ≥4.0×10^9/L or neutrophils ≥1.5×10^9/L; Platelets ≥100×10^9/L; Hemoglobin ≥90 g/L;PT or APTT ≤1.5×ULN; Total bilirubin ≤1.5×ULN; ALT/AST ≤2.5×ULN or ≤5×ULN (for liver metastasis); ALP ≤2.5×ULN (≤4.5×ULN if bone/liver metastasis); BUN ≤1.5×ULN;

Serum creatinine ≤1.5×ULN

At least one measurable lesion according to RECIST 1.1

Male participants must agree to use contraception during the study and for 6 months after

Able to understand and voluntarily sign informed consent, with good compliance

(2) Exclusion Criteria

Severe liver or renal dysfunction

Unable to lie supine for 30 minutes

Refusal to participate

Claustrophobia or psychiatric disorders

Other conditions deemed unsuitable by investigators

Study Process

- Baseline tests within 2 weeks before enrollment
- Two PET/CT scans (within 1 week interval)
- Imaging performed after tracer injection
- Image interpretation by ≥2 nuclear medicine physicians
- Follow-up within 2 months (2–3 times)

4. Participant Responsibilities:
In order to ensure the smooth and successful conduct of this study, you are required to cooperate with the following: - Follow the arrangements of the investigator to undergo examinations. - Do not change your current treatment or initiate any new treatment without consulting the study physician. - Inform the study physician of any health problems, even those you consider insignificant. - Inform the study physician of all medications used before and during the study, including traditional Chinese medicine. - If you withdraw early for any reason, you are encouraged to complete the final evaluation. - You are required to undergo routine examinations to ensure your safety.

5. Risks and Discomforts:
Possible adverse reactions include:

1) Intravenous injection may occasionally cause pain at the injection site or mild allergic reactions (such as erythema or swelling), which usually do not require special treatment and do not pose systemic risks.
2) Radiation exposure: Participants will receive a certain level of radiation. The radiation dose of each scan is approximately equivalent to that of a contrast-enhanced abdominal and pelvic CT scan.
3) Special population protection: For minors, elderly individuals, and other special populations, it is recommended to drink more water and urinate frequently on the day of examination to facilitate tracer excretion. No special measures are required for others.
4) Unknown risks: There may be risks or adverse reactions that are currently unforeseeable.
You may experience no adverse reactions or some reactions of varying severity (mild, moderate, orsevere). If any adverse events occur, your physician will provide appropriate treatment.

6. Benefits

If you agree to participate, you may receive direct medical benefit, but benefit is not guaranteed.

Information obtained may help future patients with similar conditions.

7. Alternative Options

- MRI, CT, or other imaging modalities

8. Costs

- Study-related imaging is free
- No cost to participants

9. Compensation

None

10. Injury and Compensation

Participation in this study exempts you from the cost of one PET/CT scan using 68Ga-PSMA-617 or 68Ga-FAPI-04. The cost of 68Ga-FAPI-PSMA imaging will be covered by the study. You will not bear any study-related costs.

11. Voluntary Participation

You may choose not to participate or withdraw at any time without providing any reason. Your medical care and rights will not be affected. Data collected prior to withdrawal may continue to be used in the study under confidentiality.

12. Privacy and Confidentiality

During the study, your identifiable information (such as name and gender) will be replaced by codes or numbers and kept strictly confidential. Only authorized personnel will have access. Study results may be published but will not include any identifiable personal information. By signing this consent form, you agree that authorized personnel, regulatory authorities, and ethics committees may review your medical records to ensure proper conduct of the study.

13. Contact Information

You may obtain information about the study at any time. Contact details have been anonymized.

Consent Signature Page

If you fully understand and agree to participate, please sign below.

Participant Statement

1. I have read and understood this document
2. Participation is voluntary
3. I agree my data may be reviewed under confidentiality
4. I agree to participate

Participant Name: _____
Date: _____

Legal Representative: _____
Date: _____

Investigator Statement

I confirm that the study has been explained to the participant, including risks and alternatives.

Investigator Name: _____
Date: _____