

scenario name

Prospective Clinical Study of 18F-FAPi PET Imaging Combined with Multi-Parameter MRI in the Diagnosis and Treatment of Gastric Cancer

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Clinical Research Unit: The First Affiliated Hospital of Zhejiang University School of Medicine

Study sponsor: Chen Donghe

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Revision History

edition	date	imprint
1.0	2025-11-24	first draft

List of Multicenter Clinical Trial Sites

Research Principal Investigator and Principal Research Institution Information

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Join event list

Center number	Clinical Trial Institution Name
01	Zhejiang Provincial People's Hospital
02	Shulan (Hangzhou) Hospital
03	
04	
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Researcher's Statement and Signature Page

This study is a prospective clinical trial, and the methodologies, equipment, and medications employed have been widely adopted in clinical practice. A rigorous adverse event monitoring system will be established to meticulously record all adverse events and ensure timely and effective management. In the event of any serious or significant adverse event, regardless of its association with the study intervention or whether any intervention procedures have been performed, the study sponsor must be promptly notified, and a decision to terminate the study will be made based on the circumstances. The investigators guarantee strict confidentiality of participants' personal data: all participant information and imaging will be labeled with numbers rather than names; identifiable information will not be disclosed to members outside the research team unless the participant consents; all study members and sponsors are required to adhere to confidentiality principles; all study records will be stored in locked filing cabinets for researchers' access only; during and after the study, government regulatory authorities or ethics committee members may conduct random checks on participants' personal data as per regulations; no personal information will be disclosed upon publication of the study results.

Researcher's signature

I have read and agreed to the protocol proposed in this document, and acknowledge the relevant content thereof. During the trial, I will strictly comply with the laws, regulations, and relevant rules of the People's Republic of China, fulfill my duties as a research participant, and adhere to confidentiality requirements.

Research institution: The First Affiliated Hospital of
Zhejiang University School of Medicine

Name of investigator: Chen Donghe

Researcher Position: Associate Chief Physician

Researcher's signature:

Date of signature:

scenario summary

Study name	Prospective clinical study of 18F-FAPI PET combined with multi-parameter MRI in the diagnosis and treatment of gastric cancer
Study protocol	This study adopted a prospective, multicenter, observational research design. It aimed to evaluate the diagnostic and therapeutic research of 18F-FAPI PET/CT combined with multiparameter MRI in gastric cancer patients. A total of 230 subjects were planned to be enrolled from three centers nationwide (The First Affiliated Hospital of Zhejiang University School of Medicine, Zhejiang Provincial People's Hospital, and Shulan Hangzhou Hospital).
research design	perspective study
Number of research centers	3
sample capacity	230
indicatio	patients with suspected or confirmed gastric cancer who have undergone 18F-FAPI PET/CT and MRI (non-contrast + contrast-enhanced scans)
purpose of research	The purpose of this study was to evaluate the diagnostic efficacy and prognostic value of 18F-FAPI PET/CT combined with multiparameter MRI in gastric cancer.
primary end point	Diagnostic efficacy of 18F-FAPI PET/CT combined with multiparameter MRI in gastric cancer (sensitivity, specificity, accuracy)
Selection criteria	(1) Patients suspected or diagnosed with gastric cancer (2) 18F-FAPI PET/CT has been performed (3) Gastric MRI with both non-contrast and contrast-enhanced scans performed
exclusion criteria	(1) Concurrent presence of other active malignant tumors or a history of other malignant tumors within the past 5 years; (2) Severe uncontrollable diseases or active infections; (3) Ineligible participants who cannot provide informed consent for the study; (4) Patients with suboptimal image quality in 18F-FAPI PET/CT (5) Patients with suboptimal MRI image quality enhancement
study termination criteria	1. Achieve the research objectives; 2. Occurrence of severe adverse events
18F-FAPI Instructions	The Nuclear Medicine PET Center holds a Class IV Certificate for Radioactive Drugs, enabling independent production and research of radiopharmaceuticals for scientific purposes. 18F-FAPI is a routinely performed tracer in our hospital, with over 1,800 cases of 18F-FAPI PET/CT scans completed to date, primarily including gastric cancer, pancreatic cancer, colorectal cancer, and head and neck tumors.

Visit Plan	For patients under treatment and follow-up at this hospital, no in-person visits are required; relevant data can be obtained from the electronic medical record (EMR) system and imaging system of this hospital. For patients not receiving treatment at this hospital, a telephone follow-up protocol is implemented to obtain relevant pathological results.
research report	The study plans to enroll 230 eligible patients within 3 years, followed up their pathological results, and conduct statistical analysis.
statistical analysis	Statistical analysis was performed using SPSS 17.0. The diagnostic sensitivity, specificity, and negative/positive predictive values were calculated using a four-cell table. The area under the ROC curve and the optimal cutoff value (SUV optimal cutoff) were evaluated by ROC curve analysis. The consistency between 18F-FAPI PET combined with multiparametric MRI diagnosis and pathological diagnosis was assessed using the kappa test. A p-value <0.05 was defined as statistically significant.

English abbreviation reference

PET	Positron emission tomography
CT	Computed tomography
ROC	Receiver operating characteristic curve
FAPI	Fibroblast activation protein inhibitor
MRI	Magnetic Resonance Imaging

1 Research Background

1.1 Current Status of Gastric Cancer

As one of the most common malignant tumors worldwide, gastric cancer imposes a significant public health burden due to its high incidence and mortality rates. According to the latest statistics from the International Agency for Research on Cancer (IARC) of the World Health Organization, gastric cancer ranks fifth in incidence among all malignant tumors and fourth in mortality, causing approximately 760,000 deaths annually, which exerts heavy pressure on both patients' quality of life and social healthcare resources. Gastric cancer exhibits distinct regional distribution patterns globally, with East Asia being particularly prominent. Epidemiological studies indicate that China, as a high-incidence country for gastric cancer, faces immense challenges in prevention and control due to factors such as a large population base and uneven regional development, among which the low rate of early diagnosis is a key factor constraining the improvement of 5-year survival rates for gastric cancer patients. Throughout the clinical diagnosis and treatment process of gastric cancer, accurate early diagnosis, precise preoperative staging, effective efficacy evaluation, and reliable prognosis prediction constitute critical steps in improving patient outcomes.

1.2.1 Application of 18F-FAPI PET/CT in the Diagnosis of Gastric Cancer

In the field of gastric cancer diagnosis and treatment, there is an urgent demand for highly specific and sensitive molecular imaging technologies. The synthesis of 18F-FAPI probes is based on the high-affinity binding properties of fibroblast activation protein inhibitors (FAPIs) to FAP, achieving specific targeted imaging through radioactive fluorine-18 labeling. FAP, as a type II transmembrane serine protease, is specifically and highly expressed by cancer-associated fibroblasts (CAFs) in the tumor microenvironment, while it is almost not expressed in normal tissues [14][4]. This expression specificity enables 18F-FAPI to achieve excellent targeting. 18F-FAPI probes exhibit unique pharmacokinetic characteristics, including rapid blood clearance and low nonspecific binding. Clinical studies have demonstrated that high-quality images can be obtained within 1 hour after injection, with a tumor-to-background ratio (TBR) significantly superior to that of 18F-FDG. This rapid clearance not only enhances image contrast but also significantly reduces patient radiation dose.

18F-FAPI PET/CT demonstrates exceptional sensitivity and specificity in the detection of primary gastric cancer tumors, with its advantages primarily reflected in the ability to identify early lesions and the detection efficiency of specific pathological types. Multiple studies have confirmed that, compared to conventional 18F-FDG PET/CT, 18F-FAPI exhibits higher levels of radiotracer uptake in the imaging of primary gastric cancer lesions. In a prospective study, Sun et al. [32] conducted a comparative analysis of 86 patients with gastric mucinous adenocarcinoma and signet-ring cell carcinoma, finding that 68Ga-FAPI PET/CT significantly

outperformed 18F-FDG PET/CT in the detection accuracy of primary tumors, particularly in the identification of early lesions. This advantage stems from the specific expression mechanism of FAP in the tumor microenvironment—cancer-associated fibroblasts exhibit overexpression of FAP in the early stages of gastric cancer development, enabling 18F-FAPI to achieve effective targeting at the initial phase of tumor formation [2].

8F-FAPI PET/CT also demonstrates significant advantages in the assessment of gastric cancer lymph node metastasis and distant metastasis. Multiple studies have confirmed that this technique exhibits a significantly higher detection rate for metastatic lymph nodes compared to 18F-FDG PET/CT. A prospective study by Sun et al. [32] revealed that among 86 patients with gastric mucinous adenocarcinoma or signet ring cell carcinoma, 68Ga-FAPI PET/CT achieved an 87% detection accuracy rate for involved lymph nodes, markedly higher than the 71% rate of 18F-FDG PET/CT ($P < 0.001$). Notably, 18F-FAPI excels in detecting minimal lymph node metastasis, primarily due to its ability to specifically target fibroblast-activated protein (FAP), which is expressed by tumor-associated fibroblasts (CAFs). CAFs play a critical role in the tumor microenvironment, particularly in the process of lymph node metastasis [2]. In the evaluation of distant metastasis, 18F-FAPI PET/CT demonstrates exceptional capability in detecting peritoneal metastasis.

1.2.2 Diagnostic Challenges of 18F-FAPI PET/CT in Gastric Cancer

It is noteworthy that although [^{18}F]-FAPI demonstrates superior performance in detecting various metastatic types, its specificity remains challenging, particularly as FAPI uptake may also occur in benign lesions such as inflammation and fibrosis [20]. Tosunoglu et al. [20] reported a case of gastric signet ring cell carcinoma where [^{68}Ga]-FAPI-46 exhibited inflammatory uptake at the puncture site, mimicking the presentation of Sister Mary Joseph nodules. Similarly, Xu Kui et al. [16] noted in their review that FAP is also expressed in non-neoplastic conditions such as arthritis, atherosclerosis, and fibrosis, which may lead to false-positive results.

1.3.1 Research Progress of Multi-Parameter MRI in the Diagnosis of Gastric Cancer

Multiparametric magnetic resonance imaging (mpMRI) achieves a synergistic assessment of the morphological characteristics and functional status of gastric cancer by integrating multiple functional sequences, including diffusion-weighted imaging (DWI), dynamic contrast-enhanced MRI (DCE-MRI), and T2-weighted imaging [4][5]. DWI quantitatively reflects the extent of water molecule diffusion limitation

within tissues through the apparent diffusion coefficient (ADC), which is closely related to tumor cell density. DCE-MRI generates parameters such as volume transfer constant (K_{trans}) and rate constant (K_{ep}) via pharmacokinetic models, enabling non-invasive evaluation of tumor vascular permeability and blood perfusion status [6][7]. Furthermore, emerging radiomics and artificial intelligence technologies can deeply decode tumor heterogeneity by high-throughput extraction of mpMRI image features, thereby providing a more profound theoretical basis for the formulation of individualized treatment strategies [5][12].

In assessing tumor invasion depth, multiparametric MRI (MPRM) demonstrates superior soft tissue resolution and versatile imaging sequences, enabling clear differentiation of gastric wall layers to accurately determine whether the tumor is confined to the mucosal layer, infiltrates the submucosa, or extends into the muscularis and serosa. For lymph node metastasis evaluation, MPRM effectively identifies metastatic lymph nodes through comprehensive analysis of morphological features (e.g., lymph node size, shape, and margins) and functional parameters (e.g., diffusion limitation and enhancement characteristics). Diffusion-weighted imaging (DWI) sequences provide functional evidence for detecting micro-metastases by measuring apparent diffusion coefficient (ADC) values, as increased malignancy cell density typically leads to reduced ADC values. In M staging, the multi-sequence and multi-parameter characteristics of MRI offer complementary information, enhancing diagnostic accuracy for peritoneal metastases and distant lymph node metastases, particularly those involving abdominal organs such as the liver. MPRM exhibits higher sensitivity than CT, providing more comprehensive imaging evidence for clinical staging.

Low-grade gastric cancer exhibits significantly lower ADC values compared to moderately and well-differentiated gastric cancers due to its high cell density, increased nuclear-to-cytoplasmic ratio, and tight cell arrangement, which further restricts water diffusion. Giandola et al. [36] highlighted in their systematic review that ADC values play a crucial role in differentiating gastric cancers of varying grades, particularly in distinguishing low-grade adenocarcinoma from signet-ring cell carcinoma. Liu et al. [35] further confirmed that the combination of orthogonal axial magnetic resonance imaging (MRI) with quantitative ADC analysis can markedly improve the accuracy of histological grading in gastric cancer, providing an imaging basis for preoperative individualized treatment planning.

Neoadjuvant chemotherapy (NAC), as the standard treatment for locally advanced gastric cancer, requires early and accurate prediction of its efficacy to guide individualized therapeutic strategies. Multiple studies have demonstrated that multiparametric MRI (mp-MRI) can detect functional changes in the tumor microenvironment during early treatment, enabling earlier and more accurate identification of treatment responders compared to conventional anatomical imaging. Among these, the apparent diffusion coefficient (ADC) values obtained from diffusion-weighted imaging (DWI) serve as critical biomarkers for evaluating treatment response. In treatment-responsive patients, tumor cells undergo apoptosis and necrosis, leading to reduced cell density, increased extracellular space, and diminished restriction of water molecule diffusion, which is reflected as elevated ADC values on DWI.

1.3.2 Challenges in the Diagnosis of Gastric Cancer with Multi-Parameter MRI

In multi-parameter MRI imaging for gastric cancer, respiratory motion and intestinal peristalsis are critical factors affecting image quality. Due to the prolonged scanning time of upper abdominal MRI, patients cannot fully hold their breath, resulting in varying degrees of respiratory artifacts [80]. Particularly in dynamic contrast-enhanced sequences requiring multiple acquisitions, respiratory motion not only causes image blurring but also leads to quantitative analysis deviations in time-signal intensity curves [81]. Intestinal peristalsis primarily affects the accuracy of apparent diffusion coefficient measurements in diffusion-weighted imaging, producing false diffusion-limited appearances. Quantitative multi-parameter mapping protocols are particularly sensitive to motion artifacts, where even sub-voxel displacements can cause significant deviations in parameters such as relaxation time and magnetization transfer saturation [79].

Patients with gastric cancer often have implants such as surgical staplers and metal clips, which generate localized magnetic field inhomogeneities. These metallic objects not only cause signal loss and geometric distortion on conventional T1 and T2-weighted images but also significantly compromise the accuracy of quantitative imaging sequences [85]. Particularly during postoperative recurrence evaluation, metal artifacts may completely obscure subtle lesions in the anastomotic region. Furthermore, anatomical changes following gastrointestinal surgery, such as abnormal gastric emptying function and altered intestinal positioning, make standard imaging plane localization challenging, thereby increasing the risk of partial volume effects and motion artifacts [80].

1.4.1 The diagnostic efficacy of 18F-FAPI PET/CT in different gastric cancer subtypes requires further validation

Although existing studies have demonstrated the significant efficacy of 18F-FAPI PET/CT in certain tumor types, its diagnostic performance across different gastric cancer subtypes remains to be further validated. Significant biological characteristics and clinical manifestations vary among gastric cancer subtypes. Research indicates that the effectiveness of 18F-FAPI PET/CT in identifying gastric cancer subtypes has not been sufficiently clinically validated. For instance, one study revealed that the sensitivity and specificity of 18F-FAPI PET/CT in detecting gastric cancer differ from those of conventional 18F-FDG PET/CT, particularly in terms of tumor burden and metabolic activity across different subtypes [6]. Therefore, the specific diagnostic capabilities for various gastric cancer subtypes still require validation through large-scale clinical trials.

1.3.2 Consistency of Imaging Evaluation Criteria in the Assessment of Treatment Efficacy for Gastric Cancer

Currently, the most commonly used imaging evaluation standard is the Response Evaluation Criteria in Cancer (RECIST 1.1), which primarily relies on unidimensional measurements of tumor size. However, the limitation of

RECIST 1.1 lies in its insufficient consideration of the biological characteristics of tumors and the complexity of treatment responses. For instance, the introduction of immunotherapy has made tumor response patterns more complex, potentially leading to temporary increases in tumor volume. Consequently, evaluation standards such as iRECIST, which combine 18F-FAPI PET/CT with multiparametric MRI, have emerged to better reflect the efficacy of immunotherapy and account for the dynamic changes in tumor responses [7].

1.3.3 The Significance of 18F-FAPI PET/CT in Prognostic Prediction of Gastric Cancer

There is a significant correlation between imaging features and tumor mutational burden (TMB), and imaging assessment can serve as an effective tool for predicting immune therapy response [26]. This combination not only improves the accuracy of efficacy prediction but also provides new insights for personalized treatment. However, as an emerging imaging technique, 18F-FAPI PET/CT still requires further research in predicting patient prognosis and treatment response.

Based on this, the present study adopted a prospective, multicenter research design to evaluate the diagnostic efficacy and prognostic value of 18F-FAPI PET/CT combined with multiparametric MRI imaging in gastric cancer.

2 Objectives and Content of Clinical Research

2.1 Purpose of Clinical Research

The purpose of this study was to evaluate the diagnostic efficacy and prognostic value of 18F-FAPI PET/CT combined with multiparameter MRI in gastric cancer.

Primary endpoint: Diagnostic efficacy of 18F-FAPI PET/CT combined with multiparametric MRI in gastric cancer patients (sensitivity, specificity, accuracy)

secondary end points:

- ① To compare the diagnostic performance differences between 18F-FAPI PET/CT and contrast-enhanced MRI in the clinical application of gastric cancer;
- ② Analysis of diagnostic differences in the subgroup (pathological, genetic, etc.) of patients using 18F-FAPI PET/CT combined with multiparameter MRI;
- ③ Evaluation of 18F-FAPI PET/CT combined with multiparameter MRI in predicting the prognosis of gastric cancer.

2.1 Content of Clinical Studies

2.1.1 Evaluation of the diagnostic and staging efficacy of 18F-FAPI PET/CT combined with multiparametric MRI

This study aims to evaluate the sensitivity, specificity, and accuracy of 18F-FAPi PET/CT combined with multiparametric MRI in gastric cancer patients, providing a basis for clinical application. By performing 18F-FAPi PET/CT and multiparametric MRI imaging on gastric cancer patients, relevant data were collected and analyzed to assess their performance in early diagnosis, staging, and recurrence monitoring. The goal is to provide a scientific basis for clinical physicians in the diagnosis, precise staging, and treatment decision-making of gastric cancer.

2.1.2 Comparative Study of 18F-FAPi PET/CT and Contrast-Enhanced MRI

A comparative study of 18F-FAPi PET/CT and contrast-enhanced MRI in gastric cancer patients to evaluate the differences in tumor detection sensitivity, specificity, and accuracy among various imaging modalities. The study aims to clarify their advantages in clinical applications for gastric cancer. The research will focus on analyzing the differences in tumor size, location, metastasis, and pathological characteristics detected by each imaging technique, and explore the potential of 18F-FAPi PET/CT combined with multiparametric MRI in improving the diagnostic accuracy and early detection of gastric cancer.

2.1.3 Analysis of diagnostic differences in gastric cancer subgroups using 18F-FAP PET/CT combined with multiparametric MRI

Subgroup analysis was performed based on pathological type, stage, and molecular subtype, stratified by disease pathological type, stage (early/progressive/advanced), and molecular subtype, to evaluate the differences in sensitivity and specificity of 18F-FAPi PET/CT combined with multiparameter MRI across different patient populations. This study will help identify which specific types of gastric cancer patients are more likely to benefit from 18F-FAPi PET/CT, thereby providing a basis for the development of individualized treatment plans.

2.1.4 Evaluation of Multimodal Imaging Combinations in Predicting Gastric Cancer Prognosis

Based on TNM staging and PERCIST criteria, this study evaluates the post-treatment reassessment, efficacy prediction, and prognostic assessment (AUC comparison of PFS/OS) of 18F-FAPi PET/CT combined with multiparametric MRI in gastric cancer. The research aims to analyze the multimodal imaging combination's monitoring capability for tumor response post-treatment and its value in prognostic evaluation, providing clinicians with a more precise tool for therapeutic outcome assessment. It tracks the time from diagnosis to specific events (e.g., CR, PR, SD, PD, recurrence, death) in gastric cancer patients to identify influencing factors. Survival rates over time are plotted using Kaplan-Meier curves to visually compare survival differences across groups. Additionally, Cox proportional hazards model-based multivariate regression quantifies the contribution of factors such as age and pathological stage to survival risk, aiding clinical decision-making.

3 Mechanism of Action and Research Scope of 18F-FAPI PET/CT

^{18}F (97% β^+ , $T_{1/2}=109.7$ minutes) is currently the most widely used radionuclide in PET/CT due to its chemical, physical, and nuclear properties, making it an ideal choice for peptide-based imaging. ^{18}F -FDG is the most commonly used PET tracer in oncology, serving as the preferred modality for tumor diagnosis and therapeutic efficacy evaluation. However, ^{18}F -FDG PET/CT exhibits relatively low sensitivity and specificity for tumors with low invasiveness, high differentiation, or mucinous tissue, while physiological uptake in organs such as the oropharynx and digestive tract often obscures tumor metabolism and uptake. Additionally, mediastinal and hilar lymph nodes still show a high rate of false positives on ^{18}F -FDG PET, whereas ^{18}F -FAPI PET/CT improves the specificity of lymph node diagnosis. Furthermore, compared to ^{68}Ga -labeled tracers, ^{18}F -labeled FAPI has better resolution potential due to its lower positron energy. Therefore, ^{18}F -labeled FAPI holds significant clinical value and promising prospects.

4 Indications, Contraindications, and Precautions

4.1 Eligibility Criteria: Patients with suspected or confirmed gastric cancer who have undergone ^{18}F -FAPI PET/CT, MRI (non-contrast + contrast-enhanced scan)

4.2 Exclusion criteria:

- (1) Concurrent presence of other active malignant tumors or a history of other malignant tumors within the past 5 years;
- (2) Severe uncontrollable diseases or active infections;
- (3) Ineligible participants for informed consent.
- (4) Patients with suboptimal image quality in ^{18}F -FAPI PET/CT
- (5) Patients with suboptimal MRI image quality enhancement

5 、 system design

5.1 Research Methods

This study adopted a prospective, multicenter, observational research design. It aimed to evaluate the diagnostic research and exploration of multimodal imaging with ^{18}F -FAPI PET/CT combined with multiparametric MRI in gastric cancer patients. A total of 230 subjects were planned to be enrolled from three centers nationwide (The First Affiliated Hospital of Zhejiang University School of Medicine, Zhejiang Provincial People's Hospital, and Shulan Hangzhou Hospital).

5.2 Measures to Reduce or Avoid Bias

5.2.1 Blinding

No blinding.

5.2.2 Clinical Indicator Assessment

The gold standard is the pathological result of biopsy or surgery.

5.3 Subject Selection

5.3.1 Eligibility Criteria for Subjects

- (1) Patients with suspected or confirmed gastric cancer
- (2) 18F-FAPI PET/CT and gastric MRI (non-contrast + contrast-enhanced) were performed.

5.3.2 Exclusion Criteria for Subjects

- (1) Concurrent presence of other active malignant tumors or a history of other malignant tumors within the past 5 years;
- (2) Severe uncontrollable diseases or active infections;
- (3) Ineligible participants for informed consent.
- (4) Pregnant and lactating women.

5.3.3 Criteria and Procedures for Subject Withdrawal from the Study

Clinical trial personnel will collect medical history and verify the inclusion/exclusion criteria of subjects through the hospital's electronic medical record system. Subjects who do not meet the study requirements based on their personal conditions will not be approved to participate in the study.

5.3.3 Subject Loss to Follow-up

Lost to follow-up: Participants did not complete the specified follow-up period but did not 'formally' withdraw from the clinical trial.

If a participant fails to respond to three telephone follow-ups, a registered mail letter must subsequently be sent to the participant. If the participant does not respond to the letter, the participant will be considered as having "lost to follow-up" for current study visits or telephone contacts. The investigator must record this information on the original data sheet. The investigator must report this information to the relevant ethics committee in accordance with the procedures of their institution.

For cases with lost-to-follow-up, the reasons should be explained, and their e-CRF forms should be retained for review. No diagnostic efficacy statistical analysis will be performed, but the examinations will be conducted, and participation in safety analysis may be considered based on circumstances.

5.3.4 Selection Time

From January 2026 to October 2028, for a period of 3 years.

5.3.5 Number of Subjects Required for Clinical Studies

120 cases

5.4 Study Endpoints

Primary endpoint: Diagnostic efficacy of 18F-FAPI PET/CT combined with multiparametric MRI in gastric cancer patients (sensitivity, specificity, accuracy)

secondary end points:

- ① Compare the diagnostic performance differences between 18F-FAPI PET/CT and contrast-enhanced MRI in the clinical application of gastric cancer;
- ② Analysis of diagnostic differences in the subgroup (pathological, genetic, etc.) of patients using 18F-FAPI PET/CT combined with multiparameter MRI;

③ Evaluation of 18F-FAPI PET/CT combined with multiparameter MRI in predicting the prognosis of gastric cancer.

6 Research Procedures and Operational Standards

6.1 Ethical Principles and Informed Consent

Clinical studies shall commence only after the relevant materials have been approved by the ethics committee. During the implementation of the study, any revision to the protocol (excluding administrative aspects) must be re-approved by the ethics committee before proceeding with the study.

Prior to the commencement of the study, each investigator obtained written and dated approval/endorsement from the respective IEC for the study protocol (and any amendments), written informed consent, consent updates, and all other written information to be provided to the subjects. The written approval should be indicated with the final protocol version number and version date. The composition details of the IEC should be provided to the study sponsor for retention in the main study folder, including the names of the members and their roles within the committee (e.g., Chair, Expert, Founding Member).

During the study period, all documents requiring review should be submitted to the IEC by the study sponsor or investigator in accordance with national regulations.

Informed consent is a measure to protect participants. Prior to the study, investigators must provide detailed information about the clinical study to the participant or their guardian, ensuring full understanding and obtaining informed consent. The clinical study may only commence after the informed consent form has been signed.

6.2 Subject Screening

Participants will sign an informed consent form prior to enrollment in this study. Investigators will explain the nature, purpose, and risks of the study and provide the participants with an informed consent form. Participants will be given sufficient time to consider the significance of the study before deciding whether to participate. Any modifications to the informed consent form must be notified and approved by the ethics committee prior to participant enrollment.

First, participants must undergo an informed consent process and sign an informed consent form. Subsequently, eligible subjects are screened from the target population according to the pre-established inclusion and exclusion criteria of this study, after which they may be considered for inclusion in the research.

Baseline data collection included general examinations, medical history, and laboratory tests conducted at the same hospital or external hospitals within one week prior to the signing of the informed consent form. Adverse events and concomitant medications were collected after the signing of the informed consent form.

history-taking

Conduct a detailed inquiry into the patient's medical history to clarify symptoms, signs, and prior medical history (e.g., tumor history, surgical history, biopsy history, radiotherapy history, chemotherapy history, family history, allergy history, etc.), relevant laboratory tests, previous imaging findings (including plain radiography, ultrasound, CT, MRI, as well as 18F-FDG PET/CT, PET/MR, etc.), and recent pathological results (including tumor grading and Ki-67 index, etc.), along with the patient's follow-up medical records.

Image judgment criteria

The uptake of imaging agents in tissues or organs that normally do not take up such agents can be considered pathological. Typically, 18F-FAP1 is rapidly cleared from the bloodstream. Taking 18F-FAP1 as an example, radioactive distribution can be observed in the salivary glands, thyroid, liver, biliary tract, gallbladder, pancreas, adrenal glands, kidneys, intestines, collecting system, and bladder, with almost complete excretion through the biliary tract. There is minimal distribution of the radioactive imaging agent in brain tissue. Compared to the liver, if the uptake is significantly increased in a lesion, it is considered positive, suggesting malignant tumors. Generally, moderate intestinal distribution and non-focal intestinal uptake are considered non-pathological.

Record the primary lesion location, number of metastatic lesions, SUVmax, and tumor volume, among other PET parameters.

7 Statistical Considerations

7.1 Total Sample Size

Assuming we obtained the sensitivity (Se) of 0.84, specificity (Se) of 0.91, and disease prevalence (P) of 0.05 from the literature [9-11], we set the allowable error (d) to 0.08, with a confidence level of 95% ($Z=1.96$). When estimating the sample size using sensitivity, the formula yields

$$N = (1.962 \times 0.84 \times (1 - 0.84) / 0.052) = 206$$

The sample size was estimated to be 206 cases according to theoretical calculation.

In addition, based on previous studies, the potential loss-to-follow-up rate for patients is estimated to be 5%-10%. This study anticipates a 10% loss-to-follow-up rate during the clinical trial, with a calculated total sample size of 230 cases. This is a multicenter study, with 170 cases from our center (The First Affiliated Hospital of Zhejiang University School of Medicine), 30 cases from Zhejiang Provincial People's Hospital, and 30 cases from Shulan Hangzhou Hospital.

7.2 Significance Level and Confidence Interval in Clinical Research

The significance level α was set at 0.05; the confidence level was 0.95.

7.3 Statistical Methods

Statistical analysis was performed using SPSS 17.0. The diagnostic sensitivity, specificity, and negative/positive predictive values were calculated using a four-cell table. The area under the ROC curve and the optimal cutoff value (SUV optimal cutoff) were evaluated by ROC curve analysis. The consistency between 18F-FAP1 PET/CT diagnosis and pathological diagnosis was assessed using the kappa test. A p-value <0.05 was defined as statistically significant.

SPSS 17.0 was used for statistical analysis.

① Diagnostic performance evaluation, four-grid table index calculation:

Sensitivity = True positives / (True positives + False negatives) \times 100%

Specificity = True Negative / (True Negative + False Positive) \times 100%

Positive predictive value = true positive / (true positive + false positive)

Negative predictive value = true negative / (true negative + false negative)

②ROC curve analysis:

Calculate the area under the curve (AUC) and evaluate diagnostic performance (AUC>0.9 indicates excellent, 0.8-0.9 indicates good, 0.7-0.8 indicates moderate).

Determine the optimal cutoff for SUV using the maximum Youden index.

③ consistency check

The consistency between 18F-FAP1 PET/CT and pathological diagnosis was evaluated using the Kappa coefficient.

Kappa>0.8: Excellent consistency;

0.6-0.8: High consistency;

<0.6: Consistency should be interpreted with caution.

Bilateral test, $p < 0.05$ defined as significant difference.

④ survival analysis

Kaplan-Meier method:

Collect baseline PET parameters (lesion SUVmax, lesion SUVmean, MTV, LTV, bone marrow SUVmax, etc.), and plot PFS/OS curves according to treatment response (CR/PR vs. SD/PD), pathological response (e.g., MPR status), or PET parameter grouping (e.g., high/low SUVmax). Compare the significance of survival differences between groups using the Log-rank test ($p < 0.05$).

Cox proportional hazards model:

Univariate analysis: Screening of clinical variables associated with PFS/OS (age, stage, SUVmax, MTV, etc.).

Multivariate analysis: Significant univariate variables ($p < 0.1$) were included, with quantified hazard ratios (HR) and 95% confidence intervals.

Verify the proportional hazards assumption (Schoenfeld residual test).

8 Data Recording and Management

8.1 Investigator Data Records

1) For all eligible participants who have signed the informed consent form, their relevant data and laboratory test results must be meticulously and thoroughly documented.

2) All imaging data were interpreted by two attending physicians with over 5 years of experience in nuclear medicine, and the chief physician provided the final consensus interpretation for any questionable cases.

3) Original data records, signed by the investigator and dated.

4) Confirm that all adverse events have been documented, and that serious adverse events have been reported and recorded in accordance with relevant procedures in a timely manner.

9 Expected Progress of the Study

Study recruitment period: 36 months

Observational study duration: This study was an observational study, with patient mortality serving as the endpoint of follow-up.

10 Adverse Event Assessment and Reporting

10.1 Definition of Adverse Events

Adverse medical events (AMEs) in clinical trials during follow-up, including discomfort symptoms, signs or abnormal laboratory findings, and imaging abnormalities.

10.2 Major Adverse Events

New-onset clinical symptoms (e.g., fever), laboratory abnormalities (e.g., liver enzyme levels exceeding 3 times the upper limit), exacerbation of pre-existing conditions (e.g., worsening cardiac function classification), or imaging abnormalities (e.g., pneumothorax).

10.3 Documentation of General Adverse Events

All directly observed and subject-reported adverse events should be documented on the electronic case report form.

Researchers should avoid colloquial expressions and use standardized medical terminology to record adverse events, which should at least include:

- ◆ Start and end dates
- ◆ order of severity
- ◆ causality
- ◆ Measures taken
- ◆ Outcome of Adverse Events

10.4 Recording and Reporting of Serious Adverse Events

During the study period, all serious adverse events shall be immediately reported by the investigator to the attending physician or nurse-in-charge, and simultaneously submitted in writing to the clinical research management department of the affiliated clinical research institution, with written notification to the study sponsor. The clinical trial management department shall submit a written report to the relevant ethics committee and the provincial, autonomous region, or municipal food and drug administration and health and family planning authorities where the clinical research institution is located within 24 hours. For death events, the clinical research institution shall provide all required documentation to the ethics committee and the study sponsor. Contact information is as follows:

Contact	contacts	contact number	portraiture
The First Affiliated Hospital of Zhejiang University School of Medicine	Chen Donghe	13777452235	0571-87236432

10.5 Management and Follow-up of Adverse Events

10.5.1 Management of Adverse Events

In the event of any adverse event during the study, the investigator should first assess its nature and implement necessary therapeutic measures to ensure the maximum protection of the subject's rights and interests.

10.5.2 Follow-up of Adverse Events

Investigators should conduct follow-up investigations for all adverse events (including serious adverse events) and perform regular follow-ups based on the condition until the adverse event reaches its final outcome, documenting the follow-up process and the outcome of the adverse event.

11. Quality Control and Quality Assurance

11.1 Researcher Qualifications

Researchers participating in clinical studies must possess professional expertise, qualifications, and capabilities in clinical research, and pass qualification reviews. The personnel requirements should be relatively fixed.

11.2 Pre-study Researcher Training

The research team is responsible for conducting pre-study training to ensure that clinical researchers fully understand the overall study context, protocol, and related aspects.

12 Personal Data and Data Protection

All data obtained in clinical studies are protected under data protection regulations. Investigators are prohibited from disclosing the names and other personal information of subjects (excluding date of birth/age and gender).

Similarly, data storage for statistical evaluation must be conducted under the subject's study ID. Only the investigator can identify the subject's name 或其他 personal details through the study ID.

If the name of a subject needs to be identified for medical reasons during the study, all relevant personnel are obligated to maintain confidentiality.

If you save and process personal data, you should pay attention to the requirements of data protection laws.

13 Confidentiality

All participants in this clinical study should treat the purpose, content, and results of this study as confidential.

14 Data Preservation

Investigators shall properly preserve the original records, including all subjects' records, along with all relevant supporting materials, namely hospital medical records, all signed original informed consent forms, and related documentation. Investigators shall retain clinical study materials for a period of ten years after the conclusion of the clinical study.

15 Research Summary and Termination

The lead unit is responsible for completing the clinical study summary report, confirming the content of the summary report, and signing and stamping it before submitting the summary to the center. The study sponsor shall, in accordance with regulatory requirements, recover or archive all items, documents, and raw data, after which the clinical study shall be terminated.

16 Final Report and Disclosure Principles

The investigators should agree on the final study report.

The research findings may be published as scientific literature. The results may also be submitted to regulatory authorities.

17 Responsibilities of Each Party

17.1 Responsibilities of the Clinical Study Principal Investigator

- (1) Conduct standardized training for all participants to familiarize them with the study protocol, unify the operational procedures, and standardize the recording methods and evaluation criteria.
- (2) Ensure that the entire clinical research process is strictly conducted in accordance with the operational procedures.
- (3) Strictly review the entered data to ensure the completeness, authenticity, and reliability of the electronic medical record report form. Ensure the traceability of the data.

18 Qualifications of Research Centers and Investigators

All investigators and research centers participating in this study must meet the following requirements prior to obtaining eligibility for this study:

1. Qualified for 18F-FAPI PET/CT and multi-parameter MRI scanning.
2. All investigators hold GCP certificates.
3. All investigators underwent standardized training prior to the study to familiarize themselves with the relevant injection doses, procedural protocols, scanning parameters, pharmacokinetic distribution characteristics, and lesion interpretation.

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Informed Consent Form for Clinical Research Projects

Study Title: Prospective Clinical Study on the Application of 18F-FAPi PET Imaging Combined with Multi-Parameter MRI in the Diagnosis and Treatment of Gastric Cancer

Plan ID:

Version: 1.0, November 24,2025

Version number of the informed consent form: 1.1, January 10,2026

Research institution: The First Affiliated Hospital of Zhejiang University School of Medicine

Principal Investigator: Chen Donghe

Subject Name: Subject Name Abbreviation:

Subject Name: Subject Name

Abbreviation:

Subject address:

Subject phone number:

We hereby invite you to participate in a clinical study. This informed consent form provides you with information to assist in your decision regarding participation in this clinical study. Please take the time to carefully review the following content. If you have any unclear questions or terms, you may discuss them with the relevant physician.

Your participation in this study is entirely voluntary. This study has been reviewed and approved by the Hospital Clinical Research Ethics Committee—IIT Ethics Review Panel.

Research Background :

As one of the most common malignant tumors worldwide, gastric cancer imposes a significant public health burden due to its high incidence and mortality rates. According to the latest statistics from the International Agency for Research on Cancer (IARC) of the World Health Organization, gastric cancer ranks fifth in incidence among all malignant tumors and fourth in mortality, causing approximately 760,000 deaths annually, which exerts heavy pressure on patients' quality of life and social healthcare resources. Gastric cancer exhibits distinct regional distribution differences globally,

with East Asia being particularly prominent. China, as a country with a high incidence of gastric cancer, faces enormous challenges in prevention and control due to factors such as a large population base and uneven regional development.

In the field of gastric cancer diagnosis and treatment, there is an urgent demand for highly specific and sensitive imaging technologies. Multimodal imaging combinations, including molecular imaging and multi-parameter MRI, play a crucial role in the diagnosis and management of gastric cancer. 18F-FAPi PET/CT demonstrates exceptional sensitivity and specificity in the detection of primary gastric cancer tumors, with its advantages primarily reflected in the ability to identify early lesions and the efficacy in detecting specific pathological types. Compared to conventional 18F-FDG PET/CT, 18F-FAPi exhibits higher levels of radiotracer uptake in the imaging of primary gastric cancer lesions, particularly in the identification of early-stage lesions. This advantage stems from the specific expression mechanism of FAP in the tumor microenvironment—cancer-associated fibroblasts exhibit overexpression of FAP in the early stages of gastric cancer development, enabling 18F-FAPi to achieve effective targeting at the initial phase of tumor formation. 18F-FAPi PET/CT also demonstrates significant advantages in the assessment of gastric cancer lymph node metastasis and distant metastasis.

Multi-parametric magnetic resonance imaging (mpMRI) demonstrates superior soft tissue resolution and versatile imaging sequences, enabling precise differentiation of gastric wall layers to accurately determine whether tumors are confined to the mucosal layer, infiltrate the submucosa, or penetrate the muscular and serosal layers. For lymph node metastasis assessment, mpMRI effectively identifies metastatic lymph nodes through comprehensive analysis of morphological features (e.g., lymph node size, shape, and margins) and functional parameters (e.g., diffusion limitation and enhancement characteristics). Diffusion-weighted imaging sequences provide functional evidence for detecting micro-metastases by measuring apparent diffusion coefficients.

Although existing studies have demonstrated the significant efficacy of 18F-FAPi PET/CT in certain tumor types, its diagnostic performance across different gastric cancer subtypes remains to be further validated. Research indicates that the effectiveness of 18F-FAPi PET/CT in identifying gastric cancer subtypes has not been sufficiently clinically validated. Therefore, the specific diagnostic capabilities for different gastric cancer subtypes still require validation through large-scale clinical trials.

Currently, the most commonly used imaging evaluation standard is the Response Evaluation Criteria in Cancer (RECIST 1.1), which primarily relies on unidimensional measurements of tumor size. However, the limitation of RECIST 1.1 lies in its failure to adequately account for the biological characteristics of tumors and the complexity of treatment responses. For instance, the introduction of immunotherapy has made tumor response patterns more complex, potentially leading to temporary increases in tumor volume, which may be misinterpreted as disease progression under the traditional RECIST criteria. Consequently, 18F-FAPI PET/CT-based evaluation standards such as iRECIST have emerged to better reflect the efficacy of immunotherapy and account for the dynamic changes in tumor responses [7].

In the treatment of gastric cancer, the accuracy of imaging evaluation directly impacts the assessment of therapeutic efficacy. Integrating imaging evaluation with emerging biomarkers enables a more comprehensive assessment of treatment outcomes. Furthermore, there is a significant correlation between imaging features and tumor mutational burden (TMB), making imaging evaluation an effective tool for predicting immune therapy response. This combination not only enhances the accuracy of efficacy prediction but also provides new insights for personalized treatment. In summary, 18F-FAPI PET/CT, as an emerging imaging technology, combined with multi-parameter MRI imaging, holds unique potential in predicting and evaluating patient prognosis and treatment response through multimodal imaging assessment.

purpose of research :

This study aims to evaluate the diagnostic efficacy and prognostic value of 18F-FAPI PET/CT combined with multiparameter MRI in gastric cancer patients.

Research process:

This study adopted a prospective, multicenter research design. It aimed to evaluate the diagnostic research and exploration of 18F-FAPI PET/CT in lung cancer patients. A total of 230 subjects were planned to be enrolled from three centers nationwide (The First Affiliated Hospital of Zhejiang University School of Medicine, Zhejiang Provincial People's Hospital, and Shulan Hangzhou Hospital).

- (1) Indications: Patients with suspected or confirmed gastric cancer who have undergone 18F-FAPI PET/CT, gastric MRI (plain scan + contrast-enhanced scan).

- (2) Primary endpoint: Diagnostic efficacy of 18F-FAPI PET/CT combined with multiparametric MRI (sensitivity, specificity, accuracy)
- (3) Selection criteria
 - I: Patients with clinical or imaging suspicion of gastric cancer;
 - II: 18F-FAPI PET/CT scan has been performed.
 - III: Gastric MRI with both non-contrast and contrast-enhanced scans performed
- (4) exclusion criteria
 - I: Severe, uncontrollable disease or active infection;
 - II: Concurrent presence of other active malignant tumors or a history of other malignant tumors within the past 5 years;
 - III: Ineligible participants for informed consent.
 - IV: Patients with suboptimal image quality in 18F-FAPI PET/CT
 - VI: Patients with suboptimal MRI image quality enhancement
- (5) Study termination criteria: achievement of study objectives; occurrence of serious adverse events
- (6) 18F-FAPI Description: The Nuclear Medicine PET Center holds a Class IV Certificate for Radioactive Drugs, enabling independent production and development of radioactive research medications. 18F-FAPI is a routinely performed tracer in our hospital, with over 1,800 cases of 18F-FAPI PET/CT scans completed to date, primarily for pancreatic cancer, gastric cancer, colorectal cancer, and head and neck tumors.
- (7) Visit Schedule: For patients under follow-up treatment in this hospital, no in-person visits are required; relevant data can be obtained from the electronic medical record (EMR) system and imaging system of this hospital. For patients not receiving treatment in this hospital, telephone follow-up is implemented to obtain relevant pathological results.
- (8) Study plan: The study aims to enroll 230 eligible patients within 3 years, followed up their pathological outcomes and conduct statistical analysis.

- (9) Statistical analysis: Statistical analysis was performed using SPSS 17.0. The diagnostic sensitivity, specificity, and negative/positive predictive values were calculated using a four-cell table. The area under the ROC curve and the optimal cutoff value (SUV optimal cutoff value) were evaluated using the ROC curve. The consistency between 18F-FAPI PET diagnosis and pathological diagnosis was assessed using the kappa test. A p-value <0.05 was defined as statistically significant.

Specific projects in which patients participate:

- 1、 Patients clinically suspected or confirmed with gastric cancer are required to undergo contrast-enhanced MR examination and receive ¹⁸F-FAPI PET/CT scan.
 - 2、 Conduct a detailed inquiry into the patient's medical history to clarify symptoms, signs, and prior medical history (e.g., tumor history, surgical history, biopsy history, radiotherapy history, chemotherapy history, family history, allergy history, etc.), as well as relevant laboratory tests and previous imaging findings (including plain radiography, ultrasound, CT, MRI, 18F-FDG PET/CT, PET/MR, etc.).
 - 3、 For follow-up coordination, you are required to regularly provide your clinical data (e.g., treatment plans, disease progression, etc.) as per the study requirements. This collaboration is essential for completing long-term follow-up, including monitoring the subject's condition, imaging findings, pathological results (such as tumor grading and Ki-67 index), and patient treatment outcomes, to collect prognostic information.
 - 4、 ¹⁸F-FAPI PET/CT and contrast-enhanced MR examinations were completed prior to enrollment.
- After enrollment in this study, subjects were not required to undergo additional imaging or laboratory tests, only requiring follow-up without intervention to the clinical treatment plan.

Risks and Discomforts of Participation: This study is an observational study. During clinical follow-up, subjects may experience adverse medical events, including new-onset clinical symptoms (e.g., fever), laboratory abnormalities (e.g., liver enzyme levels exceeding 3 times the upper limit), exacerbation of pre-existing conditions (e.g., worsening of cardiac function classification), or imaging abnormalities (e.g., pneumothorax).

In response to potential adverse events, this clinical study has established corresponding SOP emergency procedures for adverse event management. If you experience any discomfort during the

examination, please promptly inform the clinical researcher, and we will provide timely intervention. The ^{18}F -FAPI PET/CT examination involves radioactive radiation. The physical half-life of the ^{18}F radionuclide is 108.5 minutes, and after 4-5 half-lives, the radiation is essentially completely metabolized in the body, with an effective dose of approximately 10-20 mSv, which complies with safety standards. Moreover, the radiation is rapidly metabolized, posing an extremely low risk to healthy adults. The equipment adheres to the "Radiation Protection Requirements for X-ray Computed Tomography" and complies with the principles of medical X-ray practice and protection. The ^{18}F -FAPI contrast agent generally does not cause drug adverse events, but the following risks may occur: ^{18}F -FAPI may induce mild allergic reactions such as rash and pruritus, while severe adverse reactions such as shock are rare. However, no adverse reaction events related to ^{18}F -FAPI imaging scans have been reported in domestic or international literature to date.

Alternative treatment (Are there any other medical options available to me besides participating in this study or not participating in it?): This study aims to evaluate the application value of ^{18}F -FAPI PET/CT combined with multiparameter MRI in the diagnosis of gastric cancer. It is an observational study, with particular focus on its diagnostic efficacy in gastric cancer and its role in predicting prognosis, aiming to provide a more effective diagnostic tool for clinical use. It does not involve specific treatment modalities or protocols.

The PET/CT and multiparameter MRI examinations employed in this study are mature and widely adopted diagnostic modalities, which have been incorporated into clinical guidelines for gastric cancer assessment and multiple expert consensus documents. Clinicians will select appropriate and scientifically validated examination protocols based on individual patient conditions. Patients with MRI contraindications such as claustrophobia or internal metal implants will be excluded from this study. Clinically, abdominal contrast-enhanced CT, as another universally applicable and reliable imaging technique, may be selected for gastric cancer evaluation. Existing clinical guidelines for gastric cancer diagnosis and treatment consistently emphasize the importance of abdominal contrast-enhanced CT. If a patient is not included in this study, opting for abdominal contrast-enhanced CT will not compromise the imaging assessment of gastric cancer itself.

Benefits of participating in the study:

If you agree to participate in this study, you may potentially gain direct medical benefits in the localization and characterization of tumor lesions; however, you may also not benefit, but this could be beneficial for similar patients. We hope that the information obtained from your participation in this study will be instructive for patients with the same condition in the future.

Costs associated with participating in the study: 18F-FAPI PET/CT and gastric MIR plain-scan + contrast-enhanced diagnostic methods are routinely performed in clinical practice, with application forms available for both outpatient and inpatient settings.

Compensation: None.

Compensation: During the participation in this clinical study, if you suffer any harm related to the study or experience serious adverse events, you may be entitled to corresponding compensation under the laws of China.

Right to Refuse Participation or Withdrawal from the Study: You may choose not to participate in this study or have the right to withdraw at any stage of the trial without any reason, and your medical treatment and benefits will not be affected by this decision. Once you decide to participate in this study, please sign this informed consent form to indicate your agreement. Prior to enrollment, a physician will conduct a screening to confirm whether you are a suitable candidate.

Privacy and confidentiality:

During the study period, your personal information such as name and gender will be replaced with pseudonyms or numbers and strictly confidential. Only the relevant physicians will be aware of your data, and your privacy rights will be well protected. Study conclusion

The results may be published in a journal, but no personal information will be disclosed. If you agree to participate in this study, all your medical records will be reviewed by relevant personnel from the research institution initiating this study, relevant authoritative agencies, or an independent ethics committee to assess the study's implementation.

Is it appropriate? If you have signed the informed consent form, it means you agree to allow the aforementioned personnel to review your data. How to obtain assistance in the study:

You may access relevant information and updates on this study at any time. For inquiries related to this research, please contact Chen Donghe at 87236432. Contact details for the Clinical Research

Ethics Committee—IIT Ethics Review Panel: No.79 Qingchun Road, Shangcheng District,
Hangzhou, Zhejiang Province, 0571-87233418.

Informed Consent Signature-Consent Page

If you fully understand the content of this research project and agree to participate in this study, you will sign this informed consent form in duplicate, with one copy retained by the investigator and one by the participant or their authorized representative.

Clinical Research Project Title: Prospective Clinical Study on the Application of 18F-FAP1 PET Imaging Combined with Multi-Parameter MRI in the Diagnosis and Treatment of Gastric Cancer

Signed by the subject or their legal representative:

Agree to the statement:

- 1、 I confirm that I have read and understood the informed consent form for this study, and that the potential issues and solutions during the research process have been explained to me, with the opportunity to raise my own questions.
- 2、 I have been made aware that participation in the study is voluntary and that my refusal to participate will not compromise any of my legitimate interests.
- 3、 I have been informed that the physicians participating in this study, the person in charge of this work at the First Affiliated Hospital of Zhejiang University, and the medical ethics committee have the authority to review the study records and case materials. I agree that the aforementioned personnel may directly access my study records and understand that such information will be treated confidentially.
- 4、 I agree to participate in this study

Subject signature: _____ date :

Contact information for participants:

(Note: If the subject is incapacitated or has limited capacity, the guardian's signature and date of signing are required.)

Guardian's signature:_____date :

Guardian contact information:_____Guardian and subject relationship:

(Note: If the subject is unable to read the informed consent form, an independent witness must be present to confirm that the investigator has informed the subject of all the contents of the informed consent form. The witness must sign and date the document.)

Independent Witness Signature:_____date :

Contact information for independent witnesses:

Researcher's signature:_____date :

Contact information for researchers: