BEFAST STUDY

[^{68}Ga]Ga-FAPI total body PET/CT for initial diagnosis and staging of patients with cancer in the esophagus, stomach, and pancreas

Participant information for patients with stomach or esophageal cancer

We would like to ask if you **wish to participate in a scientific study.**

Participation is voluntary, and you may withdraw your consent at any time without providing a reason.

The Purpose of the study is:

- To investigate whether 68Gallium-Gallium-FAPI ([^{68}Ga]Ga-FAPI) total body PET/CT can help improve diagnosis and staging of patients with cancer in the esophagus, stomach and pancreas.
- To examine whether [^{68}Ga]Ga-FAPI total body PET/CT can contribute to faster and more patient-friendly diagnostic imaging.

Study Plan:

If you agree to participate, you will undergo one [^{68}Ga]Ga-FAPI total body PET/CT scan and complete one questionnaire. You will spend about 2 hours at the department on the study day. The tracer [^{68}Ga]Ga-FAPI will be injected via a peripheral intravenous catheter (Venflon®) in your arm before the scan. There are no other discomforts associated with the procedures.

You can read more in the attached participant information about what the study involves, what will happen to you, and your rights if you choose to participate.

Study Location:

Rigshospitalet,
Department of Clinical Physiology and Nuclear Medicine
PET sectione 3982
Blegdamsvej 9, 2100 København Ø

[redacted]

Participant Information for a Scientific Study

Title: [^{68}Ga]Ga-FAPI Whole-Body PET/CT for Initial Diagnosis and Staging in Patients with Cancer of the Esophagus, Stomach, and Pancreas

We are contacting you because you are currently undergoing diagnostic evaluation for suspected cancer in the esophagus or stomach.

We would like to ask, if you would be interested in participating in a scientific study conducted in collaboration between physicians at Rigshospitalet and Herlev Hospital. The initiators of the project are [redacted]

Before you decide whether to participate, it is important that you fully understand the purpose of the study and what it involves. We therefore ask that you read this participant information carefully.

You will be invited to a consultation where this information will be explained in more detail, and where you will have the opportunity to ask any questions you may have. You are welcome to bring a family member or friend with you to the meeting.

The reason we are inviting you to participate in the study is that we want to further develop the diagnostic procedures that form the basis for fast and effective cancer evaluation. By participating, you can help future patients in similar situations by contributing to the development of these diagnostic methods.

If you decide to participate, we will ask you to sign a consent form. Please remember that you have the right to take time to consider your decision before signing.

Participation in the study is voluntary. You may withdraw your consent at any time, without giving a reason. This will not affect your continued treatment or follow-up care.

The reason we are inviting you to participate is that we aim to improve the diagnostic procedures used for the timely and effective evaluation of cancer. By participating, you can help future patients in similar situations by contributing to the development of these diagnostic methods.

If you decide to take part in the study, we will ask you to sign a consent form. Please remember that you are entitled to take time to consider your decision before signing.

Participation in the study is entirely voluntary. You may withdraw your consent at any time and without providing a reason. This will not affect your ongoing treatment or follow-up care in any way.

Purpose of the Study

We aim to investigate the use of whole-body PET/CT scanning with a new tracer, 68Gallium-Gallium-FAPI (abbreviated [^{68}Ga]Ga-FAPI), in patients diagnosed with cancer of the stomach and esophagus. As part of the diagnostic process for these cancers, patients typically undergo several examinations to ensure an accurate diagnosis and staging. This information helps doctors determine the most appropriate treatment.

To assess the stage of the disease, patients usually undergo a PET/CT scan using the tracer fluorine-18 Fluorodeoxyglucose (abbreviated [^{18}F]FDG), which is the standard method recommended by national clinical guidelines for suspected esophageal and gastric cancer.

Although [^{18}F]FDG PET/CT is a well-established and effective imaging method, it has certain limitations. For example, it is not ideal for detecting cancer spread to the abdominal cavity, as the tracer is also taken up by normal cells in the gastrointestinal tract, making interpretation more difficult. For this reason, patients are often offered a diagnostic procedure (laparoscopy) to rule out such spread.

[^{68}Ga]Ga-FAPI is a new PET tracer that binds to supporting cells in the microenvironment surrounding cancer cells. Unlike [^{18}F]FDG, [^{68}Ga]Ga-FAPI is not expected to be taken up by normal intestinal cells or inflammatory cells. Therefore, we hope that [^{68}Ga]Ga-FAPI will allow for more accurate detection and assessment of cancer spread in the abdominal cavity in patients with stomach and esophageal cancer, compared to current methods. There are also practical advantages to using [^{68}Ga]Ga-FAPI PET/CT, such as not requiring fasting before the scan.

This tracer has already been tested in several types of cancer, including in patients with esophageal and gastric cancer. With this study, we aim to validate the results of previous studies in a larger and more uniform patient group to confirm whether this tracer can be used effectively in the diagnostic process for patients with cancer in the esophagus and the stomach.

Rigshospitalet was among the first institutions worldwide to install a total-body PET/CT scanner in the autumn of 2021. This scanner offers several benefits compared to conventional PET/CT scanners. It covers a larger portion of the body, resulting in higher-quality images. It also enables faster scanning, potentially matching the image quality of standard PET/CT scans. We hope that by combining the [68Ga]Ga-FAPI tracer with total-body PET/CT, we can achieve a fast and effective imaging method for diagnosing and staging cancer patients.

We plan to include 30 patients in the study, who are currently being evaluated for suspected cancer in the esophagus or stomach. You will undergo a [^{68}Ga]Ga-FAPI total-body PET/CT scan to determine whether this method is as good as—or better than—standard imaging techniques in assessing the extent of cancer.

Study procedure

You will undergo one [^{68}Ga]Ga-FAPI total-body PET/CT scan at Rigshospitalet, Section 3982. A research staff member will welcome you at the department. You should expect to spend approximately 2 hours at the department.

Initially, a technician will insert a small plastic catheter (Venflon®) into your arm and inject the [^{68}Ga]Ga-FAPI tracer. You will then be placed in the scanner for a 65-minute scan. If you find it difficult to complete the full scan, we can perform two shorter scans of 5 minutes each. The first scan will take place within 30

minutes after the injection, and the second approximately 60 minutes after. During the waiting period, you are welcome to rest, read, or use your phone or tablet.

In addition to the PET scan, two CT scans will be performed—one of which may involve contrast. The type of CT scan depends on how recently you've had a contrast-enhanced CT and whether you can tolerate contrast agents. If a contrast-enhanced CT is needed, the contrast will be administered before the PET/CT scan.

The scanner is shaped like a deep ring, open at both ends, and covers a large area of the body—from the head to mid-thigh. You will lie on your back, and the entire area will be scanned in one session. After the scan, you will receive a questionnaire, which focus on your experience during the scan.This has to be completed immediately after the scan.

Personal Data and Medical Records

To ensure usefulness of the scan results, they must be compared with information from your electronic medical record. Therefore, study personnel will access relevant data from your medical record starting from the date you sign the consent form, and formally agree to participate, continuing up to one year after you complete the study scan.

In addition to the scan results, the data collected may include your gender, age, height, weight, blood test results, medical history, treatments, biopsy results, and surgical reports. This information will be used to ensure that the [^{68}Ga]Ga-FAPI total-body PET/CT scan can be properly conducted, analyzed and included in scientific publications. All the information from the electronic medical record will be anonymized.

We also intend to present anonymized scan images from your examination when publishing the study results. By signing the consent form, you agree to this.

By agreeing to participate and signing the consent form, you grant the study investigators and their representatives the right to access this information for the purposes of conducting, monitoring, and auditing the study. The Danish Medicines Agency, the National Committee on Health Research Ethics, and the Good Clinical Practice (GCP) Unit at the University of Copenhagen will also have access to your medical records as part of the legally required inspection of the study.

Your personal data will be securely stored at the Department of Clinical Physiology and Nuclear Medicine, Rigshospitalet. By law, the data must be retained for 25 years. If you are withdrawn from the study, your data will still be stored and used for certain analyses. However, no new data will be collected after your withdrawal.

Benefits of the Study: What We Hope to Learn

This study aims to expand our knowledge of [^{68}Ga]Ga-FAPI total-body PET/CT for the diagnosis and staging of esophageal and stomach cancer. We hope that this imaging method will contribute to faster, more accurate, and more comfortable diagnostic procedures for future cancer patients.

Please note that the scan will not affect your current diagnostic process or treatment. The scans will be reviewed by specialists in nuclear medicine and radiology. If you wish, you may receive information about your scan results at the conclusion of the study.

Side Effects, Risks, Complications, and Discomforts

The main discomfort associated with the study is the injection of the [^{68}Ga]Ga-FAPI tracer, which involves insertion of a small plastic catheter in the arm. There is a minimal risk of inflammation or bruising at the injection site. Some participants may also experience a sense of claustrophobia during the scan.

If contrast is used during the CT scan, you may experience mild side effects such as a metallic taste in the mouth or, in very rare cases, nausea. There is a small risk—less than 1%—of a serious allergic reaction to the contrast agent.

The radiation dose from the [^{68}Ga]Ga-FAPI PET/CT scan ranges from 6 to 15 mSv, depending on the type of CT scan performed. This corresponds to approximately 2 to 5 times the annual background radiation in Denmark (3 mSv). The additional radiation results in a very small increase in cancer risk compared to the

general population—estimated at 0.03% to 0.075%.

The tracer [^{68}Ga]Ga-FAPI is not yet approved for use in PET/CT scans in Denmark and is therefore considered an investigational drug. There are no known side effects associated with [^{68}Ga]Ga-FAPI, but there may be risks that are not yet identified. We ask that you inform us if you experience any health issues during or after the scan. A member of the research team will contact you by phone 24 hours after the scan to check on your well-being. If any unexpected side effects are discovered, you will be informed immediately and asked whether you wish to continue participating in the study.

As a participant in a publicly funded hospital study, you are entitled to the same rights as any other patient, including access to complaint procedures and insurance coverage. You are therefore covered by the Danish Patient Compensation. If you are unexpectedly injured during the study, please contact the designated study contact person, who will guide you through the process of contacting Danish Patient Compensation.

Withdrawal of the study:

Participation in this study is entirely voluntary. You have the right to withdraw from the study at any time, without providing a reason. If, for any reason, you are unable to complete the [^{68}Ga]Ga-FAPI total-body PET/CT scan, you will also be withdrawn from the study. Withdrawal from the study—or choosing not to participate in the first place—will not affect your ongoing treatment or diagnostic process in any way. The [^{68}Ga]Ga-FAPI total-body PET/CT scan is an additional procedure and does not replace any standard diagnostic examinations. Your continued care will be managed by your treating physicians, who will ensure that you undergo the appropriate standard diagnostic procedures. These will typically include [^{18}F]FDG PET/CT and contrast-enhanced CT scans, but may also involve other types of imaging depending on your specific clinical needs.

Financial Information

[redacted]

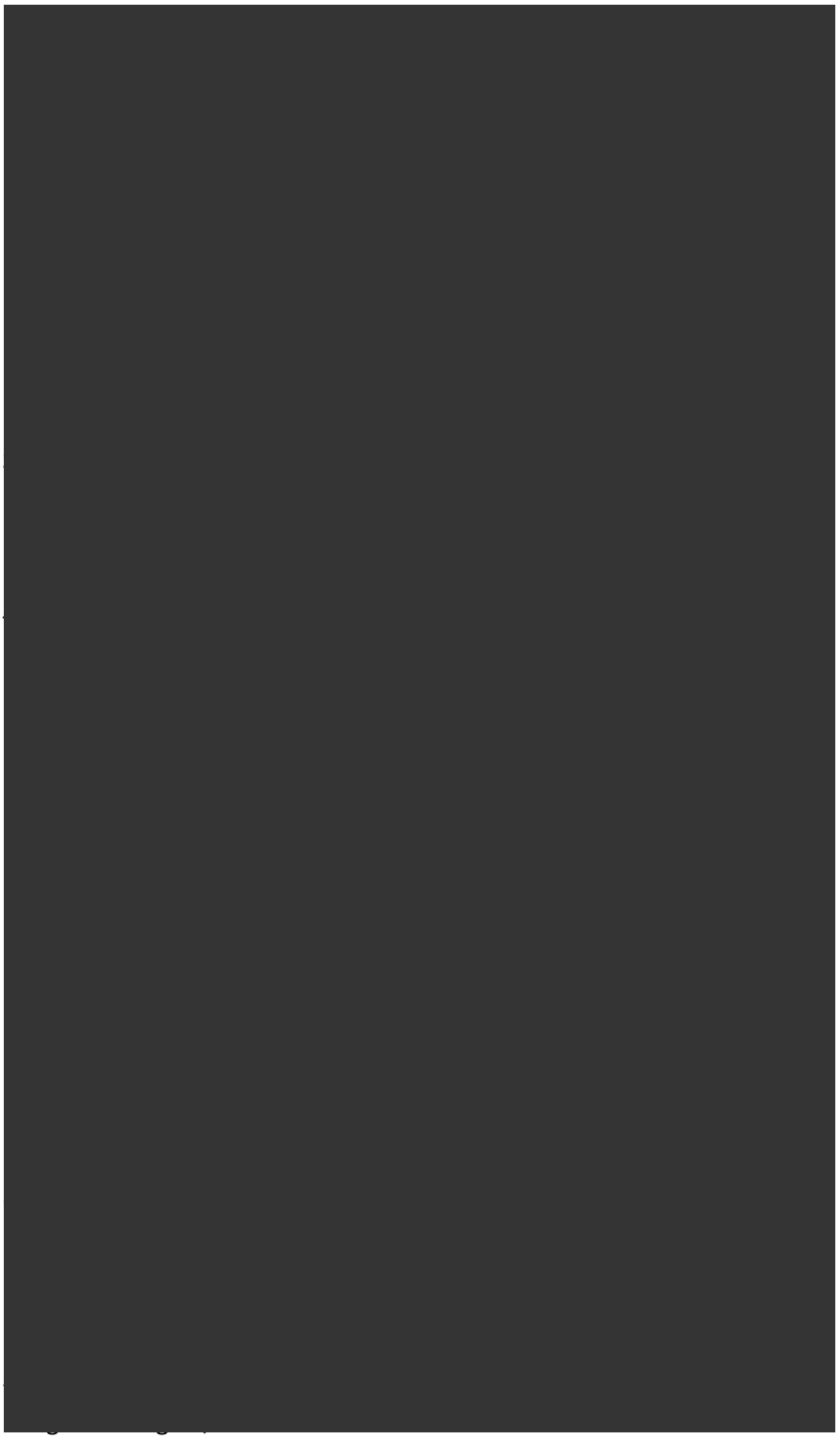
received from the Danish Cancer Society (Kræftens Bekæmpelse). None of the investigators or study personnel have any financial ties or other affiliations with the Danish Cancer Society. For more detailed information about the financial aspects of the study, please refer to the attached Appendix 1: “Financial Information.”

Access to Study Results

The results of the study will be published in the European Clinical Trial Information System (CTIS). You can access the results on their website: https://euclinicaltrials.eu/search-clinical-trials-reports/
by searching for the study’s EU trial number: 2023-503632-41-01.

The results will be made public at the conclusion of the study, which is one year after the last participant has been scanned. Additionally, the findings will be published in international scientific journals in English. Preliminary and final results may also be presented at international conferences. You have the right to request access to the study protocol. If you wish to do so, please contact the study team.

We hope this information has given you a clear understanding of what participation in the study entails and that you feel well-informed to make your decision. We also encourage you to read the attached Appendix 2: “Your Rights as a Research Participant in Clinical Trials.” If you would like to know more about



Appendix 1: Financial information

[redacted]

Hospital. Funding for the PhD fellowship for Marie Kirkegaard Stolberg is provided by grants from the Danish Cancer Society (Kræftens Bekæmpelse). The cost of the tracer used in the study is also covered by these grants. Remaining expenses will be sought from external funding sources. Operational costs related to the total-body PET/CT scans, as well as salary for the sponsor/principal investigator, are covered by the Department of Clinical Physiology and Nuclear Medicine at Rigshospitalet. The Danish Cancer Society has donated a fixed amount to support one PhD fellowship and the execution of two studies, of which this is one. The total donation amounts to 2,165,000 DKK, which is paid to the Department of Clinical Physiology and Nuclear Medicine. The department is responsible for distributing the funds across the various budget items. Any unused funds will be returned to the Danish Cancer Society. None of the investigators or study personnel have any financial ties or other affiliations with the Danish Cancer Society.

NATIONALT CENTER FOR ETIK

10. maj 2023

Your rights as a participant in other trials involving humans, tissue, cells or trials with medicinal products approved under the directive (reported to The Regional Scientific Ethics Committees)

If you are participating in a health science research project, it is important that you are aware of your rights. You can read about them on this page.

As a participant in a health science research project, you should know that:

1. Your participation in the research project is entirely voluntary and can only occur after you have received both written and oral information about the research project and signed the consent form.
2. You have the right to bring a family member, friend, or acquaintance to the information meeting.
3. You have the right to a reflection period before signing the consent form.
4. You can withdraw your consent to participate at any time, verbally, in writing, or by any other clear indication, and exit the research project. If you withdraw your consent, it does not affect your right to current or future treatment or other rights you may have.
5. The processing of information about you, including information in your blood samples and tissue, is done according to the rules in the General Data Protection Regulation, the Data Protection Act, and the Health Act. The data controller in the trial must inform you more about your rights under the data protection rules.
6. Your consent to participate in the study allows the principal investigator and sponsor to access information about your health from medical record systems when necessary for quality control and monitoring of the study.
7. If the health information collected during the study is later used by the principal investigator for research or statistical purposes, you will not be able to object to the processing or sharing of this information.
8. You have the right to decline receiving any potential new health-related information about yourself that may arise during the study and is not directly related to the study itself.
9. There is the possibility to access trial protocols under the provisions of the Public Access to Information Act. This means you can access all papers regarding the arrangement of the trial, except for parts containing trade secrets or confidential information about others.
10. There is the possibility to complain and receive compensation according to the rules in the law on complaints and compensation access within the healthcare system. If an injury occurs during the trial, you can contact the Patient Compensation Association, see more at www.patienterstatningen.dk

11. Once the study is completed, you have the right to receive information about the study's results.
12. The principal investigator is responsible for ensuring that an information resource is made available to you, where you can obtain further details about the study.

[1] Regulation (EU) 2016/679 – General Data Protection Regulation (GDPR)
This regulation governs the protection of natural persons with regard to the processing of personal data and the free movement of such data. It strengthens individuals' rights, introduces new rights (such as data portability and the right to be forgotten), and imposes obligations on organizations to ensure transparency, security, and accountability in data processing. It applies directly across all EU member states and is considered one of the most comprehensive data protection laws globally.

Danish Act No. 502 of 23 May 2018 – Supplementary Provisions to the GDPR
This national law complements the GDPR in Denmark. It outlines specific rules for the processing of personal data, including provisions for video surveillance, data concerning deceased persons (which are protected for 10 years), and manual data disclosures between public authorities. It also designates the Danish Data Protection Agency (Datatilsynet) as the supervisory authority.

Regulation (EU) 2017/745 – Medical Device Regulation (MDR)
This regulation updates and replaces previous directives on medical devices. It introduces stricter requirements for clinical evaluation, post-market surveillance, and conformity assessments. It also expands the scope to include products without a medical purpose (e.g., cosmetic contact lenses) and software as medical devices. The MDR aims to improve patient safety and ensure consistent standards across the EU.

Regulation (EU) No 536/2014 – Clinical Trials Regulation
This regulation governs clinical trials of medicinal products for human use in the EU. It replaces Directive 2001/20/EC and introduces a harmonized framework for trial authorization, ethical review, and transparency. It establishes the Clinical Trials Information System (CTIS) as a single EU-wide portal for trial submissions and public access to trial data. The regulation ensures participant safety, streamlines multinational trial processes, and enhances public trust in clinical research.

(S1)

(S1) Informed Consent for Participation in a Health Science Research Project

Title of the Research Project: **[^{68}Ga]Ga-FAPI total body PET/CT for Initial Diagnosis and Staging in Patients with Cancer of the Esophagus, Stomach, and Pancreas**

Declaration by the Participant:
I have received both written and verbal information and understand the purpose, methods, benefits, and potential risks well enough to agree to participate.

I understand that participation is voluntary, and that I may withdraw my consent at any time without losing my current or future rights to treatment.

I consent to participate in the research project and have received a copy of this consent form as well as the written information about the project for my own records.

Participant's name: _____

Date: _____ Signature: _____

Would you like to be informed about the results of the research project and any potential implications for you?
Yes _____(x) No _____(x)

Declaration by the person providing the information:
I declare that the participant has received both oral and written information about the study.

To the best of my knowledge, sufficient information has been provided to allow an informed decision about participation in the study.

Name of the person providing the information:
Date: Signature:

Project identification:
Version 5, May 2024
EU trial number: 2023-503632-41-01

BEFAST STUDY

[^{68}Ga]Ga-FAPI total body PET/CT for initial diagnosis and staging of patients with cancer in the esophagus, stomach, and pancreas

Participant information for patients with stomach or esophageal cancer

We would like to ask if you **wish to participate in a scientific study.**

Participation is voluntary, and you may withdraw your consent at any time without providing a reason.

The Purpose of the study is:

- To investigate whether 68Gallium-Gallium-FAPI ([^{68}Ga]Ga-FAPI) total body PET/CT can help improve diagnosis and staging of patients with cancer in the esophagus, stomach and pancreas.
- To examine whether [^{68}Ga]Ga-FAPI total body PET/CT can contribute to faster and more patient-friendly diagnostic imaging.

Study Plan:

If you agree to participate, you will undergo two [^{68}Ga]Ga-FAPI total body PET/CT scan on two separate days and complete one questionnaire. You will spend about 2 hours at the department on the study day. The tracer [^{68}Ga]Ga-FAPI will be injected via a peripheral intravenous catheter (Venflon®) in your arm before the scan. There are no other discomforts associated with the procedures.

You can read more in the attached participant information about what the study involves, what will happen to you, and your rights if you choose to participate.

Study Location:

Rigshospitalet,
Department of Clinical Physiology and Nuclear Medicine
PET sectione 3982
Blegdamsvej 9, 2100 København Ø

Participant Information for a Scientific Study

Title: [^{68}Ga]Ga-FAPI Whole-Body PET/CT for Initial Diagnosis and Staging in Patients with Cancer of the Esophagus, Stomach, and Pancreas

We are contacting you because you are currently undergoing diagnostic evaluation for suspected cancer in the esophagus or stomach.

We would like to ask, if you would be interested in participating in a scientific study conducted in collaboration between physicians at Rigshospitalet and Herlev Hospital. The initiators of the project are [redacted]

Before you decide whether to participate, it is important that you fully understand the purpose of the study and what it involves. We therefore ask that you read this participant information carefully.

You will be invited to a consultation where this information will be explained in more detail, and where you will have the opportunity to ask any questions you may have. You are welcome to bring a family member or friend with you to the meeting.

The reason we are inviting you to participate in the study is that we want to further develop the diagnostic procedures that form the basis for fast and effective cancer evaluation. By participating, you can help future patients in similar situations by contributing to the development of these diagnostic methods.

If you decide to participate, we will ask you to sign a consent form. Please remember that you have the right to take time to consider your decision before signing.

Participation in the study is voluntary. You may withdraw your consent at any time, without giving a reason. This will not affect your continued treatment or follow-up care.

The reason we are inviting you to participate is that we aim to improve the diagnostic procedures used for the timely and effective evaluation of cancer. By participating, you can help future patients in similar situations by contributing to the development of these diagnostic methods.

If you decide to take part in the study, we will ask you to sign a consent form. Please remember that you are entitled to take time to consider your decision before signing.

Participation in the study is entirely voluntary. You may withdraw your consent at any time and without providing a reason. This will not affect your ongoing treatment or follow-up care in any way.

Purpose of the Study

We aim to investigate the use of whole-body PET/CT scanning with a new tracer, 68Gallium-Gallium-FAPI (abbreviated [^{68}Ga]Ga-FAPI), in patients diagnosed with cancer of the stomach and esophagus. As part of the diagnostic process for these cancers, patients typically undergo several examinations to ensure an accurate diagnosis and staging. This information helps doctors determine the most appropriate treatment.
To assess the stage of cancer, patients usually undergo a PET/CT scan using the tracer fluorine-18 Fluorodeoxyglucose (abbreviated [18F]FDG). To evaluate the progression of the cancer during the course of treatment, a CT scan is frequently performed. This is standard procedure for all patients with suspected cancer of the esophagus and stomach, according to the national clinical guidelines.

Although [^{18}F]FDG PET/CT is a well-established and effective imaging method, it has certain limitations. For example, it is not ideal for detecting cancer spread to the abdominal cavity, as the tracer is also taken up by normal cells in the gastrointestinal tract, making interpretation more difficult. For this reason, patients are often offered a diagnostic procedure (laparoscopy) to rule out such spread.

[^{68}Ga]Ga-FAPI is a new PET tracer that binds to supporting cells in the microenvironment surrounding cancer cells. Unlike [^{18}F]FDG, [^{68}Ga]Ga-FAPI is not expected to be taken up by normal intestinal cells or inflammatory cells. Therefore, we hope that [^{68}Ga]Ga-FAPI will allow for more accurate detection and assessment of cancer spread in the abdominal cavity in patients with stomach and esophageal cancer, compared to current methods. There are also practical advantages to using [^{68}Ga]Ga-FAPI PET/CT, such as not requiring fasting before the scan.

This tracer has already been tested in several types of cancer, including in patients with esophageal and gastric cancer. With this study, we aim to validate the results of previous studies in a larger and more uniform patient group to confirm whether this tracer can be used effectively in the diagnostic process for patients with cancer in the esophagus and the stomach.

Rigshospitalet was among the first institutions worldwide to install a total-body PET/CT scanner in the autumn of 2021. This scanner offers several benefits compared to conventional PET/CT scanners. It covers a larger portion of the body, resulting in higher-quality images. It also enables faster scanning, potentially matching the image quality of standard PET/CT scans. We hope that by combining the [68Ga]Ga-FAPI tracer with total-body PET/CT, we can achieve a fast and effective imaging method for diagnosing and staging cancer patients.

We plan to include 30 patients in the study, who are currently being evaluated for suspected cancer in the esophagus or stomach. You will undergo two [^{68}Ga]Ga-FAPI total-body PET/CT scan to determine whether this method is as good as—or better than—standard imaging techniques in assessing the extent of cancer.

Study procedure

You will undergo two whole-body [68Ga]Ga-FAPI PET/CT scans, scheduled across two separate study days.The scans will take place at Rigshospitalet, Section 3982, where you will be welcomed by a research staff member. Please set aside approximately 2 hours for each study visit.

At the beginning of each visit, a biomedical laboratory technician or radiographer will insert a plastic catheter (Venflon®) into your arm and inject the [^{68}Ga]Ga-FAPI tracer. You will then be placed in the scanner for a 65-minute scan. If you find it difficult to complete the full scan, we can perform two shorter scans of 5 minutes each. The first scan will take place within 30 minutes after the injection, and the second approximately 60 minutes after. During the waiting period, you are welcome to rest, read, or use your phone or tablet. In addition to the PET scan, two CT scans will be performed—one of which may involve contrast. The type of CT scan depends on how recently you've had a contrast-enhanced CT and whether you can tolerate contrast agents. If a contrast-enhanced CT is needed, the contrast will be administered before the PET/CT scan.

The scanner is shaped like a deep ring, open at both ends, and covers a large area of the body—from the head to mid-thigh. You will lie on your back, and the entire area will be scanned in one session.

One the first visit, after the project scan, you will receive a questionnaire, which focus on your experience during the scan. This must be completed immediately after the scan.

Personal Data and Medical Records

To ensure usefulness of the scan results, they must be compared with information from your electronic medical record. Therefore, study personnel will access relevant data from your medical record starting from the date you sign the consent form, and formally agree to participate, continuing up to one year after you complete the study scan.

In addition to the scan results, the data collected may include your gender, age, height, weight, blood test results, medical history, treatments, biopsy results, and surgical reports. This information will be used to ensure that the [^{68}Ga]Ga-FAPI total-body PET/CT scan can be properly conducted, analyzed and included in scientific publications. All the information from the electronic medical record will be anonymized.

We also intend to present anonymized scan images from your examination when publishing the study results. By signing the consent form, you agree to this.

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Your personal data will be securely stored at the Department of Clinical Physiology and Nuclear Medicine, Rigshospitalet. By law, the data must be retained for 25 years. If you are withdrawn from the study, your data will still be stored and used for certain analyses. However, no new data will be collected after your withdrawal.

Benefits of the Study: What We Hope to Learn

This study aims to expand our knowledge of [^{68}Ga]Ga-FAPI total-body PET/CT for the diagnosis and staging of esophageal and stomach cancer. We hope that this imaging method will contribute to faster, more accurate, and more comfortable diagnostic procedures for future cancer patients.
Please note that the scan will not affect your current diagnostic process or treatment. The scans will be reviewed by specialists in nuclear medicine and radiology. If you wish, you may receive information about your scan results at the conclusion of the study.

Side Effects, Risks, Complications, and Discomforts

The main discomfort associated with the study is the injection of the [^{68}Ga]Ga-FAPI tracer, which involves insertion of a small plastic catheter in the arm. There is a minimal risk of inflammation or bruising at the injection site. Some participants may also experience a sense of claustrophobia during the scan.
If contrast is used during the CT scan, you may experience mild side effects such as a metallic taste in the mouth or, in very rare cases, nausea. There is a small risk—less than 1%—of a serious allergic reaction to the contrast agent.

The radiation dose from the [^{68}Ga]Ga-FAPI PET/CT scan ranges from 6 to 15 mSv, depending on the type of CT scan performed. This corresponds to approximately 2 to 5 times the annual background radiation in Denmark (3 mSv). The additional radiation from the two project scans result in a very small increase in cancer risk compared to the general population—estimated at 0.06% to 0.15%.

The tracer [^{68}Ga]Ga-FAPI is not yet approved for use in PET/CT scans in Denmark and is therefore considered an investigational drug. There are no known side effects associated with [^{68}Ga]Ga-FAPI, but there may be risks that are not yet identified. We ask that you inform us if you experience any health issues during or after the scan. A member of the research team will contact you by phone 24 hours after both project scans to check on your well-being. If any unexpected side effects are discovered, you will be informed immediately and asked whether you wish to continue participating in the study.

As a participant in a publicly funded hospital study, you are entitled to the same rights as any other patient, including access to complaint procedures and insurance coverage. You are therefore covered by the Danish Patient Compensation. If you are unexpectedly injured during the study, please contact the designated study contact person, who will guide you through the process of contacting Danish Patient Compensation.

Withdrawal of the study:

Participation in this study is entirely voluntary. You have the right to withdraw from the study at any time, without providing a reason. If, for any reason, you are unable to complete the [^{68}Ga]Ga-FAPI total-body PET/CT scan, you will also be withdrawn from the study. Withdrawal from the study—or choosing not to participate in the first place—will not affect your ongoing treatment or diagnostic process in any way. The [^{68}Ga]Ga-FAPI total-body PET/CT scan is an additional procedure and does not replace any standard diagnostic examinations. Your continued care will be managed by your treating physicians, who will ensure that you undergo the appropriate standard diagnostic procedures. These will typically include [^{18}F]FDG PET/CT and contrast-enhanced CT scans, but may also involve other types of imaging depending on your specific clinical needs.

Financial Information

[redacted]

funded by grants received from the Danish Cancer Society (Kræftens Bekæmpelse). None of the investigators or study personnel have any financial ties or other affiliations with the Danish Cancer Society. For more detailed information about the financial aspects of the study, please refer to the attached Appendix 1: “Financial Information.”

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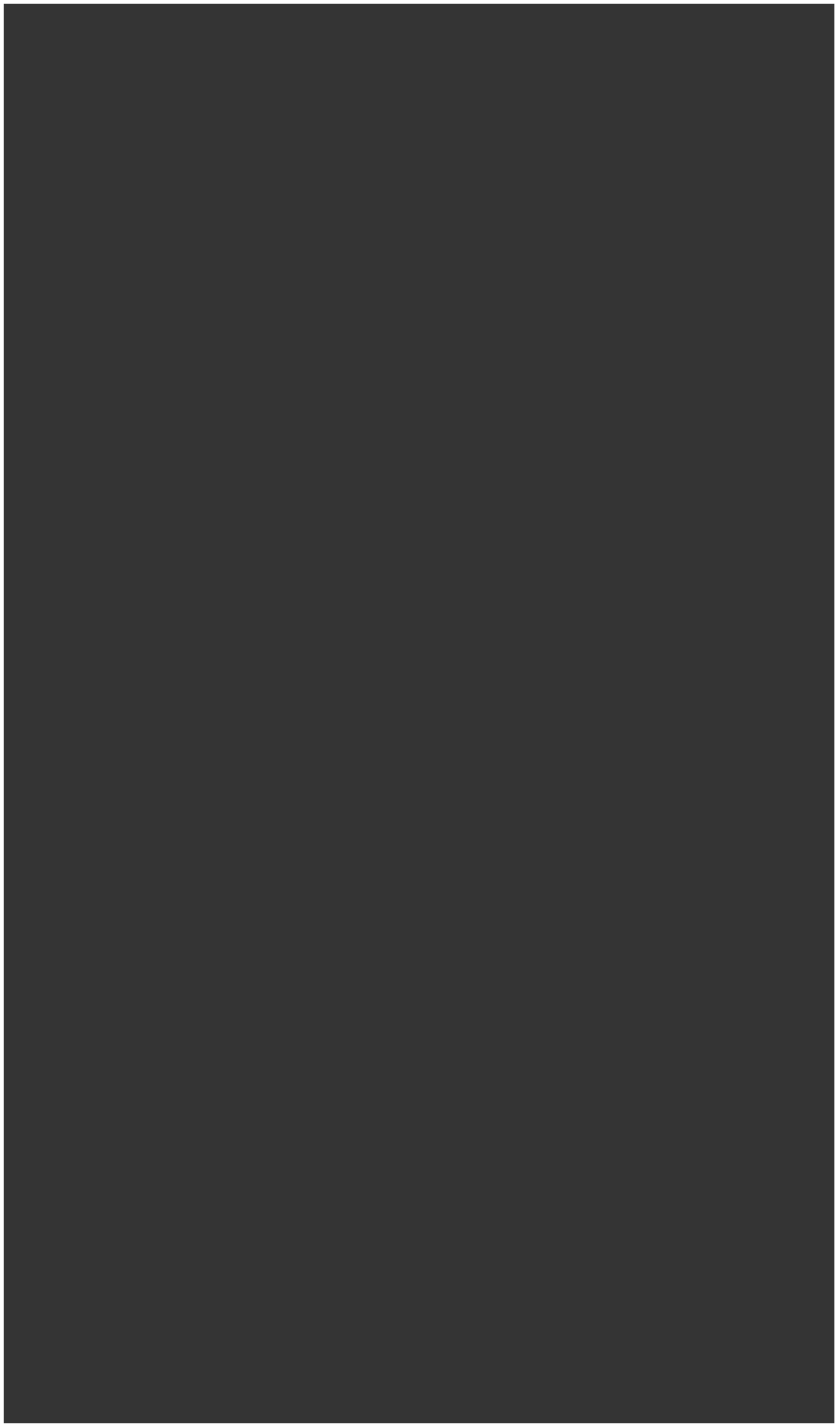
We hope this information has given you a clear understanding of what participation in the study entails and that you feel well-informed to make your decision. We also encourage you to read the attached Appendix 2: "Your Rights as a Research Participant in Clinical Trials." If you would like to know more about the study, please feel free to contact the study team.

Kind regards,



Appendix 1: Financial information

The initiators of the study are Professor and Chief Physician Barbara Malene Fischer and Physician and PhD-student Marie Krarup Stolberg. All individuals involved in the study are employed at Rigshospitalet or Herlev Hospital. Funding for the PhD fellowship for Marie Krarup Stolberg is provided by grants from the Danish Cancer Society (Kræftens Bekæmpelse). The cost of the tracer used in the study is also covered by these grants. Remaining expenses will be sought from external funding sources. Operational costs related to the total-body PET/CT scans, as well as salary for the sponsor/principal investigator, are covered by the Department of Clinical Physiology and Nuclear Medicine at Rigshospitalet. The Danish Cancer Society has donated a fixed amount to support one PhD fellowship and the execution of two studies, of which this is one. The total donation amounts to 2,165,000 DKK, which is paid to the Department of Clinical Physiology and Nuclear Medicine. The department is responsible for distributing the funds across the various budget items. Any unused funds will be returned to the Danish Cancer Society. None of the investigators or study personnel have any financial ties or other affiliations with the Danish Cancer Society.

NATIONALT CENTER FOR ETIK

10. maj 2023

Your rights as a participant in other trials involving humans, tissue, cells or trials with medicinal products approved under the directive (reported to The Regional Scientific Ethics Committees)

If you are participating in a health science research project, it is important that you are aware of your rights. You can read about them on this page.

As a participant in a health science research project, you should know that:

1. Your participation in the research project is entirely voluntary and can only occur after you have received both written and oral information about the research project and signed the consent form.
2. You have the right to bring a family member, friend, or acquaintance to the information meeting.
3. You have the right to a reflection period before signing the consent form.
4. You can withdraw your consent to participate at any time, verbally, in writing, or by any other clear indication, and exit the research project. If you withdraw your consent, it does not affect your right to current or future treatment or other rights you may have.
5. The processing of information about you, including information in your blood samples and tissue, is done according to the rules in the General Data Protection Regulation, the Data Protection Act, and the Health Act. The data controller in the trial must inform you more about your rights under the data protection rules.
6. Your consent to participate in the study allows the principal investigator and sponsor to access information about your health from medical record systems when necessary for quality control and monitoring of the study.
7. If the health information collected during the study is later used by the principal investigator for research or statistical purposes, you will not be able to object to the processing or sharing of this information.
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11. Once the study is completed, you have the right to receive information about the study's results.
12. The principal investigator is responsible for ensuring that an information resource is made available to you, where you can obtain further details about the study.

[1] Regulation (EU) 2016/679 – General Data Protection Regulation (GDPR)
This regulation governs the protection of natural persons with regard to the processing of personal data and the free movement of such data. It strengthens individuals' rights, introduces new rights (such as data portability and the right to be forgotten), and imposes obligations on organizations to ensure transparency, security, and accountability in data processing. It applies directly across all EU member states and is considered one of the most comprehensive data protection laws globally.

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This national law complements the GDPR in Denmark. It outlines specific rules for the processing of personal data, including provisions for video surveillance, data concerning deceased persons (which are protected for 10 years), and manual data disclosures between public authorities. It also designates the Danish Data Protection Agency (Datatilsynet) as the supervisory authority.

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(S1)

(S1) Informed Consent for Participation in a Health Science Research Project

Title of the Research Project: **[^{68}Ga]Ga-FAPI total body PET/CT for Initial Diagnosis and Staging in Patients with Cancer of the Esophagus, Stomach, and Pancreas**

Declaration by the Participant:
I have received both written and verbal information and understand the purpose, methods, benefits, and potential risks well enough to agree to participate.

I understand that participation is voluntary, and that I may withdraw my consent at any time without losing my current or future rights to treatment.

I consent to participate in the research project and have received a copy of this consent form as well as the written information about the project for my own records.

Participant's name: _____

Date: _____ Signature: _____

Would you like to be informed about the results of the research project and any potential implications for you?
Yes _____(x) No _____(x)

Declaration by the person providing the information:
I declare that the participant has received both oral and written information about the study.

To the best of my knowledge, sufficient information has been provided to allow an informed decision about participation in the study.

Name of the person providing the information:
Date: Signature:

Project identification:
Version 5, May 2024
EU trial number: 2023-503632-41-01

BEFAST STUDY

[^{68}Ga]Ga-FAPI total body PET/CT for initial diagnosis and staging of patients with cancer in the esophagus, stomach, and pancreas

Participant information for patients with suspected pancreatic cancer

We would like to ask if you **wish to participate in a scientific study.**

Participation is voluntary, and you may withdraw your consent at any time without providing a reason.

The Purpose of the study is:

- To investigate whether 68Gallium-Gallium-FAPI ([^{68}Ga]Ga-FAPI) total body PET/CT can help improve diagnosis and staging of patients with cancer in the pancreas, stomach, and esophagus.
- To examine whether [^{68}Ga]Ga-FAPI total body PET/CT can contribute to faster and more patient-friendly diagnostic imaging.

Study Plan:

If you agree to participate, you will undergo one [^{68}Ga]Ga-FAPI total body PET/CT scan and complete one questionnaire. You will spend about 2 hours at the department on the study day. The tracer [^{68}Ga]Ga-FAPI will be injected via a peripheral intravenous catheter (Venflon®) in your arm before the scan. There are no other discomforts associated with the procedures.

You can read more in the attached participant information about what the study involves, what will happen to you, and your rights if you choose to participate.

Study Location:

Rigshospitalet,
Department of Clinical Physiology and Nuclear Medicine
PET sectione 3982
Blegdamsvej 9, 2100 København Ø

Participant Information Regarding Participation in a Scientific Study

Title: [^{68}Ga]Ga-FAPI Total Body PET/CT for Initial Diagnosis and Staging in Patients with Cancer in the Esophagus, Stomach, and Pancreas

We are contacting you because you have been offered surgery due to a suspected cancer in your pancreas.

We would like to ask if you would be interested in participating in a scientific study conducted in collaboration between doctors at Rigshospitalet and Herlev Hospital. The initiators of the project are Barbara [redacted]

Before you decide whether to participate in the study, it is important that you fully understand the purpose of the study and what it involves. We therefore ask that you read this participant information carefully.

You will be invited to a consultation where this information will be explained in more detail, and where you will have the opportunity to ask any questions you may have. You are welcome to bring a family member or friend with you to the meeting.

The reason we are inviting you to participate in the study is that we want to further develop the diagnostic procedures that form the basis for fast and effective cancer evaluation. By participating, you can help future patients in similar situations by contributing to the development of these diagnostic methods. If you decide to participate, we will ask you to sign a consent form. Please remember that you have the right to take time to consider your decision before signing.

Participation in the study is voluntary. You may withdraw your consent at any time, without giving a reason. This will not affect your continued treatment or follow-up care.

The Purpose of the study

We aim to investigate the scanning method known as total body PET/CT using the new tracer 68Gallium-Gallium-FAPI (abbreviated [^{68}Ga]Ga-FAPI) in patients undergoing surgery for pancreatic cancer.

As part of the diagnostic process for pancreatic cancer, patients undergo various examinations to achieve an accurate diagnosis and staging. This may include CT or MRI scans. Based on this, doctors can determine the appropriate treatment. Although these imaging methods are well-established and effective, they have certain limitations — for example, they are not well-suited for assessing the spread of cancer cells to the peritoneum. When evaluating other types of cancer diagnostically, PET/CT scans using the tracer fluorine-18 Fluor-Deoxy-Glucose (abbreviated [^{18}F]FDG) are commonly used. However, [^{18}F]FDG PET/CT is rarely used for pancreatic cancer because the tracer is taken up by inflammatory cells, which are often present in pancreatic cancer. This makes interpretation of the scan more difficult. Neither is [^{18}F]FDG PET/CT effective in evaluating cancer spread to the peritoneum. The reason is that the [^{18}F]FDG tracer is also taken up by normal cells in the intestinal tract as well, making it hard to distinguish between cancer tissue and normal tissue.

[^{68}Ga]Ga-FAPI is a new PET tracer that binds to supporting cells in the microenvironment surrounding cancer cells. Unlike [^{18}F]FDG, [^{68}Ga]Ga-FAPI is not expected to be taken up by normal intestinal cells or inflammatory cells. Therefore, we hope that [^{68}Ga]Ga-FAPI will allow for more accurate diagnosis and assessment of disease spread in the abdominal cavity in patients with pancreatic cancer compared to

existing methods. There are also practical advantages of the [^{68}Ga]Ga-FAPI PET/CT scan, such as not requiring fasting before the scan.

The tracer [^{68}Ga]Ga-FAPI has already been tested in several types of cancer, including pancreatic cancer. In this study, we aim to validate findings from previous research by applying the method to a larger and more uniform group of patients, to confirm whether this tracer is suitable for evaluating pancreatic cancer.

Rigshospitalet was among the first institutions worldwide to install a total-body PET/CT scanner in the autumn of 2021. This scanner offers several benefits compared to conventional PET/CT scanners. It covers a larger portion of the body, resulting in higher-quality images. It also enables faster scanning, potentially matching the image quality of standard PET/CT scans. We hope that by combining the [^{68}Ga]Ga-FAPI tracer with total-body PET/CT, we can achieve a fast and effective imaging method for diagnosing and staging cancer patients.

We plan to include 30 patients in the study, all of whom are scheduled for curative surgery. You will undergo a [^{68}Ga]Ga-FAPI total-body PET/CT scan before your operation to determine whether this method is as good as—or better than—standard imaging techniques in assessing the extent of cancer.

Study procedure

You will undergo one [^{68}Ga]Ga-FAPI total-body PET/CT scan at Rigshospitalet, Section 3982. A research staff member will welcome you at the department. You should expect to spend approximately 2 hours at the department.

Initially, a technician will insert a small plastic catheter (Venflon®) into your arm and inject the [^{68}Ga]Ga-FAPI tracer. You will then be placed in the scanner for a 65-minute scan. If you find it difficult to complete the full scan, we can perform two shorter scans of 5 minutes each. The first scan will take place within 30 minutes after the injection, and the second approximately 60 minutes after. During the waiting period, you are welcome to rest, read, or use your phone or tablet.

In addition to the PET scan, two CT scans will be performed—one of which may involve contrast. The type of CT scan depends on how recently you've had a contrast-enhanced CT and whether you can tolerate contrast agents. If a contrast-enhanced CT is needed, the contrast will be administered before the PET/CT scan.

The scanner is shaped like a deep ring, open at both ends, and covers a large area of the body—from the head to mid-thigh. You will lie on your back, and the entire area will be scanned in one session. After the scan, you will receive a questionnaire, which focus on your experience during the scan.This has to be completed immediately after the scan.

Personal Data and Medical Records

To ensure usefulness of the scan results, they must be compared with information from your electronic medical record. Therefore, study personnel will access relevant data from your medical record starting from the date you sign the consent form, and formally agree to participate, continuing up to one year after you complete the study scan.

In addition to the scan results, the data collected may include your gender, age, height, weight, blood test results, medical history, treatments, biopsy results, and surgical reports. This information will be used to ensure that the [^{68}Ga]Ga-FAPI total-body PET/CT scan can be properly conducted, analyzed and included in scientific publications. All the information from the electronic medical record will be anonymized.

We also intend to present anonymized scan images from your examination when publishing the study results. By signing the consent form, you agree to this.

By agreeing to participate and signing the consent form, you grant the study investigators and their representatives the right to access this information for the purposes of conducting, monitoring, and auditing the study. The Danish Medicines Agency, the National Committee on Health Research Ethics, and the Good Clinical Practice (GCP) Unit at the University of Copenhagen will also have access to your medical records as part of the legally required inspection of the study.

Your personal data will be securely stored at the Department of Clinical Physiology and Nuclear Medicine, Rigshospitalet. By law, the data must be retained for 25 years. If you are withdrawn from the study, your data will still be stored and used for certain analyses. However, no new data will be collected after your withdrawal.

Benefits of the Study: What We Hope to Learn

This study aims to expand our knowledge of [^{68}Ga]Ga-FAPI total-body PET/CT for the diagnosis and staging of pancreatic cancer. We hope that this imaging method will contribute to faster, more accurate, and more comfortable diagnostic procedures for future cancer patients.

Please note that the scan will not affect your current diagnostic process or treatment. The scans will be reviewed by specialists in nuclear medicine and radiology. If you wish, you may receive information about your scan results at the conclusion of the study.

Side Effects, Risks, Complications, and Discomforts

The main discomfort associated with the study is the injection of the [^{68}Ga]Ga-FAPI tracer, which involves insertion of a small plastic catheter in the arm. There is a minimal risk of inflammation or bruising at the injection site. Some participants may also experience a sense of claustrophobia during the scan.

If contrast is used during the CT scan, you may experience mild side effects such as a metallic taste in the mouth or, in very rare cases, nausea. There is a small risk—less than 1%—of a serious allergic reaction to the contrast agent.

The radiation dose from the [^{68}Ga]Ga-FAPI PET/CT scan ranges from 6 to 15 mSv, depending on the type of CT scan performed. This corresponds to approximately 2 to 5 times the annual background radiation in Denmark (3 mSv). The additional radiation results in a very small increase in cancer risk compared to the general population—estimated at 0.03% to 0.075%.

The tracer [^{68}Ga]Ga-FAPI is not yet approved for use in PET/CT scans in Denmark and is therefore considered an investigational drug. There are no known side effects associated with [^{68}Ga]Ga-FAPI, but there may be risks that are not yet identified. We ask that you inform us if you experience any health issues during or after the scan. A member of the research team will contact you by phone 24 hours after the scan to check on your well-being. If any unexpected side effects are discovered, you will be informed immediately and asked whether you wish to continue participating in the study.

As a participant in a publicly funded hospital study, you are entitled to the same rights as any other patient, including access to complaint procedures and insurance coverage. You are therefore covered by the Danish Patient Compensation. If you are unexpectedly injured during the study, please contact the designated study contact person, who will guide you through the process of contacting Danish Patient Compensation.

Withdrawal of the study:

Participation in this study is entirely voluntary. You have the right to withdraw from the study at any time, without providing a reason. If, for any reason, you are unable to complete the [^{68}Ga]Ga-FAPI total-body PET/CT scan, you will also be withdrawn from the study. Withdrawal from the study—or choosing not to participate in the first place—will not affect your ongoing treatment or diagnostic process in any way. The [^{68}Ga]Ga-FAPI total-body PET/CT scan is an additional procedure and does not replace any standard diagnostic examinations. Your continued care will be managed by your treating physicians, who will ensure that you undergo the appropriate standard diagnostic procedures. These will typically include contrast-enhanced CT scans, but may also involve other types of imaging depending on your specific clinical needs.

Financial Information

The initiators of [redacted]iduals involved in the study are employed at Rigshospitalet or Herlev Hospital. The project is primarily funded by grants received from the Danish Cancer Society (Kræftens Bekæmpelse). None of the investigators or study personnel have any financial ties or other affiliations with the Danish Cancer Society. For more detailed information about the financial aspects of the study, please refer to the attached Appendix 1: “Financial Information.”

Access to Study Results

The results of the study will be published in the European Clinical Trial Information System (CTIS). You can access the results on their website: https://euclinicaltrials.eu/search-clinical-trials-reports/
by searching for the study’s EU trial number: 2023-503632-41-01.

The results will be made public at the conclusion of the study, which is one year after the last participant has been scanned. Additionally, the findings will be published in international scientific journals in English. Preliminary and final results may also be presented at international conferences. You have the right to request access to the study protocol. If you wish to do so, please contact the study team.

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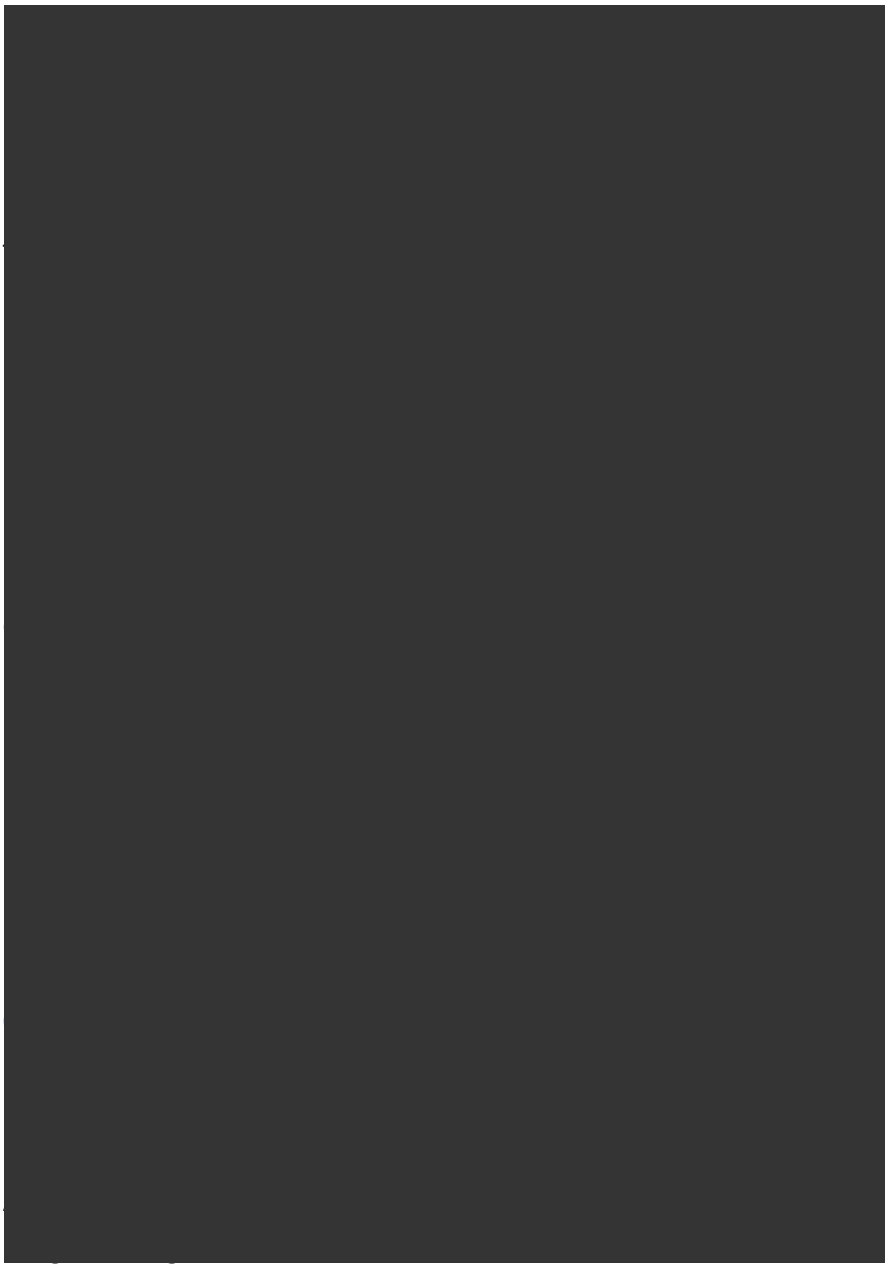

Appendix 1: Financial information

[redacted]

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NATIONALT CENTER FOR ETIK

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I consent to participate in the research project and have received a copy of this consent form as well as the written information about the project for my own records.

Participant's name: _____

Date: _____ Signature: _____

Would you like to be informed about the results of the research project and any potential implications for you?
Yes _____(x) No _____(x)

Declaration by the person providing the information:
I declare that the participant has received both oral and written information about the study.

To the best of my knowledge, sufficient information has been provided to allow an informed decision about participation in the study.

Name of the person providing the information:
Date: Signature:

Project identification:
Version 4, September 2023
EU trial number: 2023-503632-41-01