A feasibility study to suppress myocardial [18F]-FDG uptake by pre-administration of pure caffeine

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To investigate the tolerability and effect of pure cafeine food suplement pre-administration on myocardial [18F]FDG uptake suppression.

Ethical review	Approved WMO
Status	Pending
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON51725

Source
ToetsingOnline

Brief title
PET Caffeine study

Condition

- Myocardial disorders
- Autoimmune disorders

Synonym
cardiac inflammation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Caffeine, FDG-uptake, Myocard, PET scan

Outcome measures

Primary outcome

To investigate the effect of pure caffeine food supplement on myocardial

[18F]FDG uptake suppression and extra-cardiac image quality between the study

PET/CT and the routine PET/CT in the same patient.

Secondary outcome

To monitor the safety and tolerability of pure caffeine food supplement in

combination with [18F]FDG.

To measure the effect of the additional caffeine on blood glucose and FFA.

To gain insight in the physiological uptake pattern uptake due inadequate

myocardial suppression.

Study description

Background summary

[18F]FDG PET/CT has an increasingly relevant role in diagnosis and treatment management of cardiac inflammation and infection imaging. Cells involved in the inflammatory process have an increased glucose consumption and accompanying [18F]FDG uptake. Physiological [18F]FDG uptake occurs also in the normal myocardium. This uptake can be reduced by dietary manipulation, extended fasting and intravenous heparin before the administration of [18F]FDG. Although, administration of heparin carries a risk of heparin induced thrombocytopenia and bleeding. A safer alternative to stimulate free fatty acid levels and lipolysis is administration of caffeine anhydrous. This approach have never been tested for [18F]FDG PET/CT. Therefore, this pilot study will investigate the tolerability and effect of pure cafeine food supplement on myocardial [18F]FDG uptake suppression.

Study objective

To investigate the tolerability and effect of pure cafeine food suplement pre-administration on myocardial [18F]FDG uptake suppression.

Study design

This pilot study will compare the myocardial [18F]FDG uptake suppression between a study PET/CT with the standard carbohydrate restricted diet and a food supplement containing 200 mg pure caffeine one hour before [18F]FDG injection and the inadequate routine PET/CT prepared with standard carbohydrate restricted diet.

Intervention

The patients will receive one hour before the [18F]FDG injection a tablet with 200 mg of the food supplement pure caffeine.

Study burden and risks

- In this study 10 adult patients with inadequate myocardial [18F]FDG suppression on their routine [18F]FDG PET/CT, despite correctly fulfilling of the carbohydrate restricted diet.
- Patients will be asked to keep a record of the food and drinks they had during the 24 hours before the appointment.
- Patients will be asked to drink only water instead of water, coffee and thee during the two hours before the appointment.
- Patients will receive a 200 mg tablet of pure caffeine food supplement one hour before [18F]FDG injection..
- Heart rate and blood pressure wil be measured before caffeine, before [18F]FDG and after PET/CT. If SBP>150 and DBP.90 before administration of the caffeine, the patient will be excluded.
- For blood glucose comparison an extra blood sample will be taken before taking the caffeine tablet out of the venous cannula that will be placed for the [18F]FDG administration.
- For FFA comparison extra blood samples will be taken before caffeine and [18F]FDG out of the venous cannula.
- Patients will be asked to fill in a questionnaire concerning symptoms and mood before caffeine, before [18F]FDG and after PET/CT.
- According to the European Food Safety Authority (EFSA) will a single dose of caffeine up to 200 mg do not give rise to safety concerns for the general healthy adult population.
-Expected side effect of 200 mg caffeine intake is:
Slightly increase of blood pressure (systolic blood pressure 3-8 mmHg, diastolic blood pressure 4-6 mmHg). The effect of this increase is to be of low clinical relevance for healthy individuals in the general population under normal environmental conditions.
- The patient will receive a radiation burden of the additional thoracal

[18F]FDG PET/CT that is expected to be in the range of 4.0 mSv (3.0 mSv contributing to [18F]FDG and 1.0 mSv contributing to the low dose CT) for an average sized adult. This is within category IIb of the 2016 NCS report: Human exposure to ionizing radiation for clinical and research purposes: radiation dose & risk estimates This is justified as the benefits of this study directly aimed at improvement of diagnosis, which is a category IIb justification.
- The patient will have direct benefits of participation in this study. Due to myocardial [18F]FDG uptake, their routine exam was not able to exclude myocardial involvement. In systematic sarcoidosis it is reported that 2-7 % of the patients have myocardial involvement In cardiac sarcoidosis only 5% of the patients show clinical symptoms at the beginning of the disease. Therefore, early recognition of silent cardiac disease is very important for patients to start with medication to prevent serious adverse cardiac events. The only way to detect cardiac inflammation in the earliest stage is [18F]FDG. Early detection is also important in systematic vasculitides. Since, cardiac involvement is also present in less than 10% of the patients and can cause adverse cardiac events. In our study, the re-exam with additional caffeine might provide sufficient [18F]FDG myocardial uptake reduction to exclude or determine silent myocardial involvement in the patients. This will improve the diagnosis for the patient. Furthermore, if the patient will be diagnosed with silent myocardial involvement, this will change the treatment management and possibly prevent adverse cardiac events in the future.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Recent routine [18F]FDG PET/CT at Erasmus MC with inadequate myocardial [18F]FDG suppression.
Signed informed consent
Extra-cardiac lesions
Age >= 18 years
Willing to undergo the study procedures

Exclusion criteria

Pregnancy or breastfeeding
History of heart failure
Uncontrolled or untreated hypertension
Hypersensitivity for caffeine
Use of Methotrexaat, Adenosine, Stiripentol, Melatonin and/or B-blocker

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2023
Enrollment:	8
Type:	Anticipated

Ethics review

Approved WMO

Date:	22-12-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL79807.078.22