Validation of [18F]FES for imaging of brain estrogen receptors

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The primary objective of the study is to validate the use of a reference tissue model and an image derived input function for the quantification of estrogen receptors in the human brain, by [18F]FES PET. The secondary objective is to determine...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON37068

Source
ToetsingOnline

Brief title
[18F]FES for imaging of brain ER

Condition

- Other condition

Synonym
healthy controls

Health condition

gezonde deelnemers

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Brain, Estrogen receptor, Positron emission tomography, Quantification

Outcome measures

Primary outcome

The main study parameters are the binding potential and distribution volume of

[18F]FES in the human brain, derived from kinetic modelling using an arterial

input function, reference tissue modelling and an image derived input function.

Secondary outcome

A secondary study parameter is the level of estradiol in serum.

Study description

Background summary

Estrogens are the primary female sex hormones that play a major role in the development and maintenance of secondary sexual functions. In addition, estrogens play an important role in cardiovascular, musculoskeletal, immunological, bone development and central nervous system processes. Actions of estrogens are mediated by a group of specialized receptors, known as estrogen receptors. Estrogens were found to be neuroprotective and may thus protect against development of neurodegenerative disorders like Alzheimer*s disease, Parkinson*s disease and multiple sclerosis. In addition, estrogens may also play an important role in psychiatric disorders, like depression. To improve our understanding of the action of estrogens in the brain, it is important to study the expression of estrogen receptors in the brain. Positron emission tomography (PET) is the most suitable technique for non-invasive imaging of brain receptors. [18F]FES is a PET tracer that is regularly used to image the estrogen receptor expression in breast cancer patients, but has never been used for quantitative imaging of brain estrogen receptors. Quantification of the expression of brain receptors by PET usually requires arterial blood sampling to obtain the plasma input function of the tracer. Arterial blood

sampling causes discomfort to the patient and therefore can be an obstacle especially in longitudinal studies. The aim of this study is therefore to investigate whether [18F]FES PET imaging for quantification of estrogen receptors in the human brain is feasible without arterial blood sampling, using a reference tissue model (SRTM) or an image derived input function (IDIF), so the discomfort associated with arterial blood sampling can be avoided.

Study objective

The primary objective of the study is to validate the use of a reference tissue model and an image derived input function for the quantification of estrogen receptors in the human brain, by [18F]FES PET. The secondary objective is to determine whether circulating estradiol can influence quantification of estrogen receptors by [18F]FES.

Study design

Healthy pre- and postmenopausal women will be included for a dynamic [18F]FES PET scan and a MRI scan, with a maximum of one week between the PET and MRI scan. During the PET scan arterial blood samples will be taken as input for quantification of the estrogen receptors in the brain, using kinetic modelling. This golden standard quantification method will be compared with two methods that do not require blood sampling, i.e. reference tissue modelling and kinetic modelling using an image derived input function. In addition, serum estradiol levels will be measured to determine the effect of circulating estradiol on quantification of the estrogen receptors.

Study burden and risks

The subjects have to fill in a questionnaire and undergo a PET and a MRI scan. A total of 85 ml of blood will be taken for determination of serum levels of estradiol and for PET scan data-analysis. For the PET scan, the arterial catheterization can cause discomfort and the subjects are exposed to radioactivity with minor to moderate risk. The subjects will not obtain direct benefit from the study but will contribute to determining the best method for quantification of the estrogen receptor in the human brain and consequently to a reduction of discomfort for subjects that undergo a [18F]FES PET scans in future studies, if arterial blood sampling can be omitted.

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

- Female
- Age > 18 years
- For postmenopausal women: at least 1 year after menopause
- For premenopausal women: a regular menstruation
- Signed written informed consent

Exclusion criteria

- Use of estrogen receptor ligands
- History of ER-positive malignancies or breast cancer
- Use of any contraceptive drug (pill, injections or implanted)
- For postmenopausal women: (history of) estrogen replacement therapy
- Pregnancy
- History of removal of the ovaries and/or the uterus
- Current systemic and or major metabolic diseases
- Somatic, organic or neurological disorders
- Recent participation in a scientific research study (<1 year) involving radiation

- Claustrophobia
- Presence of materials in the body that can be magnetized

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2013
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	16&alfa;-[18F]fluoro-17β-estradiol
Generic name:	[18F]FES

Ethics review

Approved WMO Date:	09-08-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-02-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2012-003472-39-NL
CCMO	NL41608.042.12