Diagnostic accuracy of neuroblastoma patient imaging with [18F]mFBG PET-CT compared to [123I]mIBG scanning.

Published: 07-02-2020
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The primary objective is to compare18F-MFBG PET-CT imaging for neuroblastoma patients with the current standard of imaging, 123I-MIBG SPECT, using the SIOPEN score for skeletal lesions and the number of detected soft tissue lesions as endpoints.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON49035

Source
ToetsingOnline

Brief title
[18F]mFBG PET-CT for neuroblastoma imaging

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Neuroblastoma

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor Kinderoncologie
Source(s) of monetary or material Support: KiKa

Intervention

Keyword: Imaging, mFBG PET-CT, mIBG scan, neuroblastoma

Outcome measures

Primary outcome

The primary study endpoints are the number of lesions and sites of disease

detected with 18F-mFBG PET-CT compared to the current imaging standard of care,

123I-mIBG scan using the SIOPEN imaging scoring method for skeletal lesions and

the total number of detected soft tissue lesions

Secondary outcome

o Determine optimum imaging time of 18F-mFBG PET CT(60 min vs 120-150 min post

injection)

o Determine the estimation of radiation absorbed dose of 18F-mFBG

o Adverse events of 18F-mFBG injection and PET CT s

Study description

Background summary

123I-mIBG imaging is considered the best imaging modality in patients with neuroblastoma, however, the radioactive tracer and imaging technique (planar scintigraphy and SPECT) have several disadvantages:
* image acquisition takes a long time (+/- 2 hours)
* imaging requires two hospital visits as scanning is performed 24 hours after administration of the radioactive tracer
* false-negative scans are seen in patients because of the limited resolution of SPECT and planar scintigraphy images
* patients need medication to protect thyroid irradiation by 123I
These disadvantages might be overcome with 18F-mFBG, a slightly different radioactive tracer that can be visualised by PET-CT, which has a superior anatomical imaging capacity.
In this pilot study, the feasibility, safety and diagnostic accuracy of 18F-mFBG PET-CT will be assessed in 20 patients and compare with the 123I-mIBG

imaging.

Study objective

The primary objective is to compare18F-MFBG PET-CT imaging for neuroblastoma patients with the current standard of imaging, 123I-MIBG SPECT, using the SIOPEN score for skeletal lesions and the number of detected soft tissue lesions as endpoints.

Study design

A prospective explorative diagnostic pilot-study. In this study the accuracy of 18F-mFBG PET in the detection of neuroblastoma sites will be investigated, compared to the current imaging standard with 123I-mIBG scanning in 20 patients.

Intervention

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Study burden and risks

Possible radiation exposure of extra scan.
Duration of the dynamic scan.
Possible side effects of the 18F-mFBG tracer

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Patients with a (clinical suspicion of) neuroblastoma who are refferred for conventional [123I]mIBG imaging.
- age between 0-18 years old.
- written informed consent from patients and/or from parents or legal guardians, according to local law and regulations.

Exclusion criteria

Pregnancy of the patient
Age > 18 years

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-07-2020
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[18F]mFBG
Generic name:	[18F]mFBG
Product type:	Medicine
Brand name:	AdreView
Generic name:	(123I) Iobenguane injection solution

Ethics review

Approved WMO Date:	07-02-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	02-03-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	03-03-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-03-2021
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28070
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2019-003713-33-NL
CCMO	NL70903.041.19
OMON	NL-OMON28070