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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28070

Source
NTR

Brief title
MFBG PET-CT pilot study - neuroblastoma patient imaging -

Health condition

neuroblastoma

Sponsors and support

Primary sponsor: Prinses Máxima Centrum for pediactric cancer
Source(s) of monetary or material Support: KIKA

Intervention

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

To compare [18F]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 objective

[18F]mFBG PET-CT is probably better able to define neuroblastoma compared to the current imaging standard [123I] mIBG.

Study design

After 10 patients (6 months) and 20 patients (1 year)

Intervention

[18F]mFBG PET CT

Contacts

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Eligibility criteria

Inclusion criteria

patients with a (clinical suspicion of) neuroblastoma who are referred for [123I] mIBG imaging, 0-18 years of age

Exclusion criteria

pregnancy of the patient and above 18 years old

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2020
Enrollment:	20
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-11-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49035
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8152
CCMO	NL70903.041.19
OMON	NL-OMON49035

Study results