68Ga-SATO in paediatric neuroblastoma patient; exploratory, safety, non-randomized, open label, comparative study - GAP NBL study*

Published: 19-12-2022
Last updated: 09-11-2024

This study has been transitioned to CTIS with ID 2024-513843-10-00 check the CTIS register for the current data. Primary objective: Assess the short term safety and tolerability of 68Ga-SATO in pediatric patients with NBLSecondary objectives: -...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON51360

Source
ToetsingOnline

Brief title
68Ga-SATO antagonist in neuroblastoma

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
neuroblastoma

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor Kinderoncologie

Source(s) of monetary or material Support: bedrijf: ARICEUM Therapeutics

Intervention

Keyword: imaging, MIBG, Neuroblastoma, Satoreotide trizoxetan

Outcome measures

Primary outcome

To assess the short term safety and tolerability of 68Ga-SATO, according to

CTCAE v5.0.

Secondary outcome

- Absolute number of detected lesions and lesion localisation with 68Ga-SATO

PET/CT imaging compared to M123IBG scintigraphy.

- Absolute number of detected lesions and lesions localisation with 68Ga-SATO

PET/CT imaging compared to whole body MRI (in case available).

- Radiation absorbed dose for whole body and organs using dynamic qualitative

PET scanning.

- Evaluation of procedure time from administration of 68Ga-SATO till the end of

PET-image acquisition.

Study description

Background summary

Neuroblastoma is a relatively common malignancy in paediatric patients, with a median age at diagnosis of 18.8 months. Approximately 80% of NBL patients has MIBG positive disease. Unfortunately, both current clinical standards; imaging with M123IBG and therapy with M131IBG have several disadvantages. As an alternative, somatostatin receptor (SSTR) targeted imaging and therapy might have several benefits over MIBG. Approximately 85% of recurrent or refractory high risk neuroblastoma patients have positive SSTR2a staining at histopathology. In low-, intermediate- and high (non-refractory) risk patients,

SSTR2a expression is even higher.1 In NBL tumours with MYNC-amplification, SSTR expression is present, but to a lesser degree than in non-MYNC amplified NBL tumors.1 Besides MYNC-amplification, in high risk NBL patients (INSS stage 3 or 4) SSTR expression was an independent predictor for overall survival, potentially identifying a subgroup of high risk NBL patients with a poorer survival.1 Experience exists with a SSTR subtype 2a agonist (i.e. 68Ga-DOTATOC). However, from a physiological perspective a SSTR antagonist (i.e. 68Ga-Satoreotide trizoxetan, abbreviated to 68Ga-SATO), targeting both activated as non-activated SSTR2a, seems better than a SSTR2a agonist.
With this observational pilot study, primarily we wish to assess the safety of the new imaging radiopharmaceutical, SSTR-antagonist 68Ga-SATO and secondary, compare its diagnostic accuracy to current clinical standard M123IBG and whole body MRI (the latter in case of availability).

Study objective

This study has been transitioned to CTIS with ID 2024-513843-10-00 check the CTIS register for the current data.

Primary objective:
Assess the short term safety and tolerability of 68Ga-SATO in pediatric patients with NBL

Secondary objectives:
- Comparison of 68Ga-SATO PET/CT imaging to the current clinical standard of M123IBG scintigraphy in NBL patients, in terms of lesions detection.
- Comparison of 68Ga-SATO PET/CT imaging to whole body MRI (in case available), in terms of lesions detection.
- To calculate, in a subset of patients, the radiation absorbed dose of 68Ga-SATO for patients using dynamic PET imaging.
- Evaluation of procedure time for the preparations and acquisition of a 68Ga-SATO

exploratory see protocol section 1.0 objectives

Study design

A prospective explorative, investigator initiated, pilot study investigating the accuracy and safety of 68Ga-SATO in NBL patients, compared to current clinical standard, M123IBG imaging on 20 time points.

Intervention

n.a.; an additional 68Ga-SATO PET/CT will be performed, for which the patient will receive a single bolus injection of the radiopharmaceutical via a

pre-existing intravenous cannula or via a pre-existing central line.

Study burden and risks

An additional 68Ga-SATO PET/CT will be performed, for which the patient will receive a single bolus injection of the radiopharmaceutical via a pre-existing intravenous cannula or via a pre-existing central line.
Ideally, the PET/CT scan will be performed in the same anaesthesia session (only in children requiring sedation), as the M123IBG scintigraphy, the standard diagnostic investigation. This will increase the anaesthesia time by 30-40 minutes and will require no additional placement of an intravenous cannula (for this study). Alternative logistically acceptable solutions are a) the PET/CT will be acquired on the day of M123IBG injection (day prior to M123IBG scintigraphy acquisition; not for children requiring anaesthesia) or on the day of a MRI in standard of care (for patients requiring anaesthesia), b) a separate acquisition day, not in combination with the standard diagnostic M123IBG protocol, as long as the reference test (M123IBG scintigraphy) and the 68Ga-SATO PET/CT are not more than 2 weeks apart (only for children not requiring anaesthesia).

Results of the 68Ga-SATO PET/CT will be blinded for the treating physician and will not influence treatment decision making, as the clinical value of 68Ga-SATO of any other SSTR-targeted PET/CT is unknown to date. This study will generate preliminary data for the initiation and development of future phase 2 studies in neuroblastoma.
No related adverse events are described in literature and are not expected related to 68Ga-SATO. However, adverse events possibly, probably or definitively related to the 68Ga-SATO will be monitored up to 1 hour after PET/CT acquisition (=2 hours after administration). An additional telephone visit will be planned 3-5 days after the scan to ask patients for new, unexpected adverse events.

Potential harm for the child is the additional radiation exposure of the radiopharmaceutical and additional low-dose CT. Based on data in adults, a radiation exposure of 68Ga-SATO alone is approximately 3.6 mSv for a 150 MBq injection. However, amount of activity for administration and image acquisition will be adjusted to the patients weight in this study; 2 MBq/kg (minimum of 40 MBq, maximum 150 MBq). The additional low dose CT will be approximately 2 mSv (in line with low dose CT acquisition in clinical 18FDG-PET/CT). For comparison, in small children M123IBG alone results in a radiation exposure of approx.. 3.2 mSv for the minimum dose of 80 MBq (according to SIOPEN guidelines) and in adults 68Ga-DOTATOC results in radiation exposure of approx. 3.1 mSv for a 150 MBq injection (investigational brochure and EANM guideline).

Because of the one-day imaging schedule and the shorter acquisition time, 68Ga-SATO is more convenient for patients (and parents/caregivers). No additional preparation is needed for image acquisition (no thyroid protection

from radioactive iodine, like with M123IBG or fasting for 4-12 hours, like with 18FDG).

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)
Babies and toddlers (28 days-23 months)

Inclusion criteria

- Age 0-18 years
- Written informed consent (by legal representative) and assent consent from the patient when applicable
- Patients with a clinical suspicion of neuroblastoma who are referred for the first time for conventional M123IBG imaging and patients with known NBL who are

referred for for follow-up M123IBG imaging

Exclusion criteria

- Children with pre-existing severe auto-immune diseases.
- Use of therapeutic long-acting somatostatin analogs (e.g. Sandostatin®, Lanreotide®) within the 21 days before the planned infusion of 68Ga-SATO.
- Use of diuretics within 24 hours before the planned infusion of 68Ga-SATO.
- pregnancy of the patient

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-04-2023
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	68GA- Satoreotide trizoxetan
Generic name:	68GA- Satoreotide trizoxetan
Product type:	Medicine
Brand name:	AdreView
Generic name:	(1231) lobenguane injection solution

Ethics review

Approved WMO Date:	19-12-2022
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-02-2023
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	01-08-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	12-08-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EU-CTR	CTIS2024-513843-10-00
EudraCT	EUCTR2022-001811-16-NL
CCMO	NL81980.000.22