Position stability during radiosurgery of brain tumours

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Primary objective of this study is to assess the correlation between tip of the nose motion and head motion. Secondary objective is to assess the immobilization capacity and comfort of different masks in the context of SRS with the ICON system.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational non invasive

Summary

ID

NL-OMON44274

Source
ToetsingOnline

Brief title
Position stability during SRS of brain tumours

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
Brain metastases, brain tumours

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: eigen RT research afdeling

Intervention

Keyword: Brain tumours, Position stability, Stereotactic radiosurgery

Outcome measures

Primary outcome

The correlation between nose-tip motion and position with respect to motion and position of the head of the subject. Per fraction we will have at least 18000 measurements (30 minutes x 10 Hz) based on which we can build a correlation model. Based on the EM tracking system and the CBCT data we can calculate the actual tumour displacement during a fraction. For different thresholds of actual tumour motion (0.5 mm, 1 mm, 1.5 mm, and 2 mm) we will establish the needed threshold for the HDMM system, and its accuracy in detecting the motion.

Secondary outcome

The immobilization capabilities of the different masks will be assessed as the position and orientation deviation of the three sensors on the head in time with respect to the first measurement using a rigid point match.

The comfort of the different masks will be assessed based on scoring of the volunteers. For each mask they will score the comfort on a scale of 1 to 10.

Data will be evaluated in a paired manor as this is observer dependent.

Study description

Background summary

The incidence of brain metastases has increased over time as a result of the increased use of MRI and improvements in the treatment of primary tumors and

systemic disease. When the brain metastasis are limited in size and number, stereotactic radiosurgery (SRS) is one of the main treatment options. Currently we are treating our patients with a linear accelerator (linac). After the tumor delineation, a safety margin is added to the target volume to account for patient set-up and intra-fraction motion in the actual treatment plan. An alternative irradiation delivery machine specifically designed for brain irradiation is the Gamma-Knife, known for its accurate and stable patient set-up and stability for one single fraction SRS. In the past, accuracy of SRS was guaranteed by mounting a stereotactic frame on the head of the patient. The latest Gamma Knife, the ICON, is equipped with an on-board cone-beam computed tomography (CBCT) imaging system. On this system, recently installed in our hospital, fractionated SRS is possible using a less invasive thermoplastic mask for patient set-up and immobilize the patients. During the actual SRS a reflective marker on the tip of the nose is tracked with an optical tracking system to detect any patient movement. If motion thresholds are exceeded, the SRS is stopped and setup is repeated. The standard mask for SRS provided by Elekta deviates substantially from the masks used for our linac based SRS. In this study we would like to investigate if the stability of the tip of the nose is representative for the stability of the head of the patient, and what the immobilization capacity and comfort is of different types of masks.

Study objective

Primary objective of this study is to assess the correlation between tip of the nose motion and head motion. Secondary objective is to assess the immobilization capacity and comfort of different masks in the context of SRS with the ICON system.

Study design

This will be a prospective study with a volunteer part and a patient study part. The volunteer study (colleagues) will be used to compare different masks. In the patient study we will monitor the actual head stability during SRS in comparison to the nose stability

Study burden and risks

Patients: The risks associated with participation can be considered negligible and the burden can be considered minimal.

Volunteers: three different masks will be made and the volunteer has to lay still for three times thirty minutes on three different days. They may experience some discomfort due to the mask.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
AMSTERDAM 1066CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
AMSTERDAM 1066CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient must be planned for mask based or frame based SRS on the ICON system at our institute
Patients/Volunteers must be 18 years or older
Patients/Volunteers must sign informed consent

Exclusion criteria

A contra-indication for use of the Elektromagnetic tracking system, e.g. a pacemaker.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	14-12-2017
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL62438.031.17