Precision Radiotherapy for Metastases to the Lung.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28379

Source
Nationaal Trial Register

Brief title
LUMERAS

Health condition

English: Stereotactic, Radiotherapy, Lung, Metastases, Oligometastases, CyberKnife.

Dutch: Stereotactische, Radiotherapie, Long, Uitzaaiingen, Oligometastasen, CyberKnife.

Sponsors and support

Primary sponsor: The individuals responsible for initiating and managing the study and who are responsible for ensuring that the trial is properly registered are Dr. J.J.Nuyttens and Prof.Dr. P.C. Levendag.

Source(s) of monetary or material Support: There is no funding or material support from an agency, foundation or company. The research is self-financed: Fund= initiator= sponsor.

Intervention

Outcome measures

Primary outcome

Local tumor control rate at 1 year.

Sample size was calculated with P0=70%, P1=90%, and alpha/beta =0.10.

1. P0= largest probability of Local Tumor Control that implies that therapeutic activity is too low and does not warrant further investigation;

2. P1= smallest probability of Local Tumor Control that implies that therapeutic activity is sufficient to warrant further investigation.

Secondary outcome

1. Overall surival (at one and two years);

2. Progression-free survival (at one and two years);

3. Treatment related toxicity (acute at 6 months; Late at 2 years).

Study description

Background summary

Objective:

To determine whether stereotactic radiotherapy achieves a local tumor control rate comparable to surgery (i.e. 90%) in patients with metastatic disease.

Study design:

Non-randomized, single center prospective phase II trial.

Study population:

Patients with limited metastatic lung disease who are inoperable or refuse surgery. Inclusion criteria include: a minimal life expectancy of 6 months, metastatic disease to maximum 2 organs, <5 metastatic lesions, and an interval between treatment of the primary tumor and diagnosis of the metastases of minimal 4 months.

Intervention:

1-7 fractions of stereotactic radiotherapy depending on tumor size and location. Placement of markers into/near the tumor prior to radiation therapy.

Primary outcome:

Local tumor control at one year.

Secondary outcome:

Overall and progression-free survival and
treatment-related toxicity.

Study objective

Radiotherapy involving a high biological dose with a limited treatment volume achieves a local tumor control rate of at least 90% in patients with metastatic cancer to the lung.

Study design

Timepoints of primary and secondary outcomes: See above.

Follow up:

Pulmonary function tests and CT-scans will be done four times during the first year, twice during the second year, and once during the third year of follow-up.

Intervention

Patients are treated with 1-7 fractions of stereotactic radiotherapy using the CyberKnife. The treatment schedule will depend on the tumor location and size.

1. Peripheral tumors >3cm: 3 fractions of 20 Gy (60Gy).

2. Peripheral tumors <3cm: Single dose of 30 Gy (30Gy).

3. Central tumors: 5 fractions of 12 Gy (60Gy).

4. Mediastinal tumors: 7 fractions of 8 Gy (56Gy).

Prior to treatment with the CyberKnife, markers will be placed into/or near the tumor in order to enable "tumor tracking". This enables the CyberKnife to precisely deliver a high radiation

dose.

Markers are placed using one of the following approaches: via bronchoscopy, vascular placement (catheterization), or intra- or extra-pulmonary marker placement.

No control group

Contacts

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Eligibility criteria

Inclusion criteria

1. Minimal life expectancy of 6 months;

2. WHO 0-3;

3. Metastatic disease limited to a maximum of 2 organs;

4. No more than 5 metastatic lesions and a controlled primary tumor site;

5. Diagnostic imaging includes at least a PET-scan and CT ¨Cthorax/abdomen, of which one is not older than 4 weeks at the time of referral for SBRT;

6. Primary tumor must be treated at least 4 months before the diagnosis of the metastasis;

7. Patients are discussed in a multidisciplinary team, including a pulmonologist and/or medical oncologist;

8. Patients with more than 2 lung metastases should be treated with a first line chemotherapeutical agent prior to stereotactic radiotherapy in all cases unless the patient is not suitable for chemotherapy;

9. Patients must be 18 years or older;

10. Woman with pregnancy potential must use an effective contraceptive method;

11. Patients must sign a study-specific consent form;

12. FEV1 > 40% of predicted;

13. Leukocytes > 3 x 109;

14. Thrombocytes > 100 x 109;

15. Bilirubine < 1.5 mg/dl;

16. PTT > 60%.

Exclusion criteria

1. Pregnant women;

2. Inability to lie flat for at least 90 minutes.

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:	Recruiting
Start date (anticipated):	01-03-2009
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-04-2009
Application type:	First submission

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
NTR-new	NL1687
NTR-old	NTR1788
Other	METC ErasmusMC / ABR number / file number : 2008-292 / 23450 / NL23450.078.08
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

No publications related directly to the LUMERAS study.

Publications related to CyberKnife treatment (for primary non-small cell lung cancer) at the Erasmus MC-Daniel den Hoed Cancer Center, Rotterdam, The Netherlands:

van der Voort van Zyp NC, Prevost JB, Hoogeman MS, Praag J, van der Holt B, Levendag PC, van Klaveren RJ, Pattynama P, Nuyttens JJ. "Stereotactic radiotherapy with real-time tumor tracking for non-small cell lung cancer: Clinical outcome."
Radiother Oncol. 2009 Mar 16.
PMID: 19297048

Nuyttens JJ, Prevost JB, Praag J, Hoogeman M, Van Klaveren RJ, Levendag PC, Pattynama PM. "Lung tumor tracking during stereotactic radiotherapy treatment with the CyberKnife: Marker placement and early results." Acta Oncol. 2006;45(7):961-5.
PMID: 16982564

Prevost JB, Nuyttens JJ, Hoogeman MS, Pöll JJ, van Dijk LC, Pattynama PM. Endovascular coils as lung tumour markers in real-time tumour tracking stereotactic radiotherapy: preliminary results." Eur Radiol. 2008 Aug;18(8):1569-76. Epub 2008 Apr 4.
PMID: 18389249