

Prospective study of outcome after surgery for spinal metastases

Published: 14-09-2009

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To accumulate data from patients who undergo spinal surgery for metastatic cancer, for the purposes of determining the difference in outcome between operations of varying complexity.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system, skull and spine therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON33452

Source

ToetsingOnline

Brief title

Surgery for spinal metastases

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym

secondary tumour; become generalized

Research involving

Human

Sponsors and support

Primary sponsor: National Hospital for Neurology and Neurosurgery

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cancer, metastasis, outcome, spine, surgery

Outcome measures

Primary outcome

The difference in outcome between operations of varying complexity.

Secondary outcome

Secondary goals of the study will be to compare the survival and complication rates of different tumours operated by the same method, and cost-effectiveness of such surgery.

Study description

Background summary

Spinal metastases (tumours which have spread to the spine from other sites) can be treated by surgery, but many different types of surgery are available, ranging from small operations to take samples of tissue (biopsy) to large operations to remove sections of the spine and reconstruct with metal and plastic components. The operative risk varies greatly, depending on the extent of the operation, and there is still no consensus as to which operation is best for a given patient. Surgeons vary in their management of such patients because there is no gold standard, and evidence to help choose the right operation for the right patient is lacking. In our study the primary aim is to create a database to determine the outcomes of the different extents of surgery for patients with matched tumour type and staging.

Study objective

To accumulate data from patients who undergo spinal surgery for metastatic cancer, for the purposes of determining the difference in outcome between operations of varying complexity.

Study design

Prospective study of outcome of surgery for spinal metastases.

Study burden and risks

The patients treatment and follow-up will not vary from the standard treatment provided by the centre.

Contacts

Public

National Hospital for Neurology and Neurosurgery

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London WC1N 3BG
GB

Scientific

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London WC1N 3BG
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

signed inform consent
the patient has a metastatic spinal tumour
the patient is at least 18 years old

Exclusion criteria

Patients who refuse consent for their anonymised data to be held in the database.
Patients who are unable to consent due to learning disabilities, unconsciousness, mental illness, young age or dementia.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 16-02-2010

Enrollment: 200

Type: Actual

Ethics review

Approved WMO

Date: 14-09-2009

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

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	NL27268.058.09