ACNS 0331: a study evaluating limited target volume boost irradiation and reduced dose craniospinal radiotherapy (18.00 Gy) and chemotherapy in children with newly diagnosed standard risk medulloblastoma: a phase III double randomized trial.

Published: 11-11-2009
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON35496

Source
ToetsingOnline

Brief title
ACNS 0331 Medulloblastoma SR

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain tumor, medulloblastoma

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Kinderoncologie Nederland
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: craniospinal radiotherapy, medulloblastoma

Outcome measures

Primary outcome

Efs and OS

Secondary outcome

Type of relapse

Cognitive, audiological and endocrinological outcome

Study description

Background summary

The treatment of children with a medulloblastoma with craniospinal irradiation causes severe neurotoxicity. The tumor is sensitive to chemotherapy. Research is needed to find the optimal combination of therapy.

Study objective

The aim of the study is to assess if a dose reduction of craniospinal irradiation in children with a medulloblastoma does not reduce event free survival (EFS) or overall survival (OS). Furthermore it will be assessed if a field reduction (only tumor plus marging instead of the whole posterior fossa) has effect on EFS en OS.

Study design

This is a multicentre, randomised, open, parallel-group phase III clinical

trial.

Intervention

Part 1: Chemo-radiotherapy
1. radiotherapy
Craniospinal irradiation will be given 5 times per week for a period of 6 weeks
Randomisation will determine if the patient receives 18,00 or 23,4 Gy. All patients receive 54 Gy in the tumor region. A second randomisation will determine if only the tumor + margin will be irradiated or the whole posterior fossa
2. chemotherapy
vincristin (bolus, i.v.) will be given once a week for a period of 6 weeks, starting in week 1 (1 week after start of irradiation)

Part 2: maintenance therapy

During this part of treatment only chemotherapy is given. De treatment is the same in all patients. Approximately 4 weeks after finishing the chemoradiotherapy phase, maintenance therapy wil be started.
The maintenance therapy consists of 9 courses. There are 2 different types of courses, called A and B. After 2 A courses follows a B course, which totals up to 6 A courses and 3 B courses.

Course A 42 days
CCNU (orally) day 1
Vincristin (bolus, i.v.) on day 1,8 en 15
Cisplatinum (i.v. drip) day 1

Course B 28 days
Cyclofosfamide (i.v. drip) day 1 en 2
Vincristin (bolus, i.v.) op day 1 en 8

Study burden and risks

The risks and burden of participation are similar to standard treatment. A potential benefit is les side effects of treatment. Potential risk is an increased chance of recurrence, although this is unlikely based on literature data available.

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)

Inclusion criteria

1) maximal cross-sectional area of residual tumor of 1.5 cm2 or less
2) no evidence of metastatic disease in the head, spine or CSF
3) performance level >/ 50% (Karnofsky/Lansky)
4)no previous radiotherapy or chemotherapy other than corticosteroids
5) adequate renal function
6) adequate liver function
7) adequate bone marrow function
8) no pregnancy/breast feeding
9) signed informed consent
10) national and institutional requirements for human studies must be met

Exclusion criteria

1) maximal cross-sectional area of residual tumor larger than 1.5 cm2
2) evidence of metastatic disease in the head, spine or CSF
3) performance level below 50% (Karnofsky/Lansky)

4) previous radiotherapy or chemotherapy
5) inadequate renal function
6) inadequate liver function
7) inadequate bone marrow function
8) pregnancy/breast feeding
9) no signed informed consent
10) national and institutional requirements for human studies are not met

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-12-2011
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Belustine
Generic name:	Lomustine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Cisplatin
Generic name:	Cisplatin

Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Cyclophosphamide
Generic name:	Cyclophosphamide
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Uromitexan
Generic name:	MESNA
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Vincristine
Generic name:	Vincristine sulfate
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	11-11-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-04-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-03-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-07-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	04-02-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-05-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-05-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-09-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2009-010004-28-NL
CCMO	NL23774.078.09