A Mechanistic Study of Mifamurtide (MTP-PE) In Patients With Metastatic And/Or Recurrent Osteosarcoma

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue neoplasms
Study type	Observational invasive

Summary

ID

NL-OMON42197

Source
ToetsingOnline

Brief title
MEMOS

Condition

- Musculoskeletal and connective tissue neoplasms

Synonym
bonesarcoma, osteosarcoma

Research involving
Human

Sponsors and support

Primary sponsor: University of Oxford
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: chemotherapy, mifamurtide, MTP-PE, osteosarcoma

Outcome measures

Primary outcome

Biological en radiological response

Secondary outcome

Side effects, overal survival, extra biologische variables such as

immuneresponse

Study description

Background summary

Mifamurtide is an EMA approved agent for the primairy tretament of osteosarcoma. There are many concerns on the conduct and endpoints of the registration study and thus on the true activity of thisdrug that costs around 100.000 euro per patient

Study objective

This study was set up to examen the bioogical and radilogical efficacy of mifamurtide on metastatic osteosarcoma in order to unveil the true activity of this drug The biological activity is measured through macrophage activation. That's why the biopsies are an essential part of the study.

Study design

Patients with metastases of an osteosarcoom that can be reached safely by biopsy will be treated with mifamurtide. The effect on the tumor will be measured through sequential PET-CT through biological assessment of a new biopsy after treatment.

Study burden and risks

Two biopsies may be unpleasant (pain) and there may be a risk of bleeding. however this risk has proven to be low in multiple oncology studies where this

has been practised.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. relapsed osteosarcoma (first, Second, third or any relapse, patient has recovered from chemotherapy and any other investigational drug/agent treatment, radiotherapy or surgical procedure)
2. Histological confirmed diagnosis of osteosarcoma at original presentation.
3. Tumour at biopsy accessible or resectable site
4. Progressive disease documented by imaging within 3 months of entry into the trial
5. At least one measurable lesion on CT scan (RECIST) performed in past 21 days prior to trial

entry.
6. Male or female, age 16 years or up to 65 (or 18 years and up based on institutional practice for Teenage and Young adult Cancer Patients)
7. Life expectancy of at least 3 months.
8. WHO performance score of 0 - 2.
9. The patient is willing and able to comply with the protocol and scheduled follow-up visits and examinations.
10. Written (signed and dated) informed consent.
11. Cardiac shortening fraction >= 28% or ejection fraction >= 45%
12. Renal function is adequate for ifosfamide treatment (GFR as per table below, other renal function screening tests as per local practice)

Exclusion criteria

1. Pregnant or breast-feeding woman. Men or women of childbearing potential unless effective methods of contraception are used during study treatment and for at least 7 days after the last mifamurtide dose (see section 5.1 Informed consent - Contraceptive/ Pregnancy counselling).
2. Previous treatment with mifamurtide or a mifamurtide-like drug* in a clinical trial setting for the treatment of metastatic and/or recurrent osteosarcoma in the six months prior to registration.
3. Contraindications to lung biopsies.
4. Hypersensitivity to ifosfamide or any component of the formulation.
5. Previously diagnosed brain metastases.
6. Significant active cardiac disease including: uncontrolled high blood pressure (no greater than 2 standard deviations above the mean for age for systolic blood pressure (SBP) and diastolic blood pressure (DBP), unstable angina, congestive heart failure, myocardial infarction within the previous 6 months, or serious cardiac arrhythmias and with a history of pericarditis and myocarditis
7. Treatment with any other investigational agent, or participation in another interventional clinical trial within 21 days prior to enrolment.
8. Major surgery within 21 days prior to first study biopsy
9. Currently taking high-dose non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroid treatment
10. Concurrent use of ciclosporin or other calcineurin inhibitors.
11. Any psychological, social or medical condition, physical examination finding or a laboratory abnormality that the Investigator considers would make the patient a poor trial candidate or could interfere with protocol compliance or the interpretation of trial results.
12. Any other active malignancy, with the exception of adequately treated cone-biopsied in situ carcinoma of the cervix uteri and non-melanoma skin lesions.
13. Patients who are known to be serologically positive for Hepatitis B, Hepatitis C or HIV.

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-08-2015
Enrollment:	0
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	MEPACT
Generic name:	Mifamurtide
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	20-11-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	18-08-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	25-08-2015

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	07-01-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	27-01-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	27-07-2016
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	EUCTR2012-000615-84-NL
CCMO	NL50424.058.14