An Open Label Phase II Multicentre Clinical Trial of Single Agent VELCADETM (Bortezomib) in Patients with Malignant Pleural Mesothelioma

Published: 07-09-2006
Last updated: 10-08-2024

To find activity in this new class of drugs

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mesotheliomas
Study type	Interventional

Summary

ID

NL-OMON30139

Source
ToetsingOnline

Brief title
Phase II Velcade Mesothelioma Trial

Condition

- Mesotheliomas

Synonym
pleural cancer ; mesothelioma

Research involving
Human

Sponsors and support

Primary sponsor: All Ireland Cooperative Oncology Research Group
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bortezomib, chemotherapy, mesothelioma, Velcade

Outcome measures

Primary outcome

PRIMARY ENDPOINT

Response rate. Continued accrual during the trial will be based upon the

objective response rates in the first stage of the two-stage design for

patients treated in the first or second-line settings.

Secondary outcome

SECONDARY OUTCOMES

Progression-free survival, Overall Survival.

Study description

Background summary

Malignant pleural mesothelioma (MPM) is an aggressive, rapidly lethal thoracic malignancy causally associated with asbestos exposure that is increasing in incidence in the UK and Europe. Systemic therapy is the mainstay of management; however, there exists no agreed standard of combination chemotherapy. MPM exhibits major de novo chemoresistance, probably associated with underlying defective apoptosis signalling. Novel strategies for treating this disease are urgently needed.
Velcade (Bortezomib) is a first-in-class proteosome inhibitor, now licensed for use in myeloma. Preclinical studies from Mutti and colleagues have demonstrated significant activity of single agent velcade against MPM xenografts, necessitating its clinical evaluation in both the first and second line settings.tly needed if survival is to be improved.

Study objective

To find activity in this new class of drugs

Study design

Multicentre, international, non-randomised phase II clinical trial using Simon*s 2-Stage Optimal Design.

Intervention

Bortezomib 1.6mg/m2 intravenous administration on days 1, 8, 15, 22 of a 35 day cycle, for a total of 4 cycles (20 weeks) with the option to continue therapy in responding patients until progression (at the investigators discretion).

Study burden and risks

visiting the hospital for chemotherapy and the possible side effects.
When patients give informed consent an additional puncture of the pleural tumor will be performed an two vials of blood will be examined

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Histopathological evidence of MPM
2) Performance status ECOG 0-2.
3) Adequate haematological status:
a) Haemoglobin 10g/dl or greater.
b) White cell count 1 x 109/L or greater, neutrophil count 1.5 x 109/L or greater.
4) Platelets 100 x 109 /L or greater.
5) Adequate hepatic function (AST and ALT < 3 x upper limit of normal).
6) Willing to give written informed consent to participate. Translational research will be dealt with by a separate informed consent form.
7) Where possible, pleural effusions should be drained before treatment. For uncontrollable pleural effusions (recurrent despite regular drainage), talc or tetracycline pleurodesis may be offered as per standard practice.
8) Male subject agrees to use an acceptable method of birth control for the duration of the study and contraception must be used by women of child bearing potential

Exclusion criteria

1)Enrollment in another clinical trial.
2) The patient has a history of prior malignant tumour, unless the patient has been without evidence of disease for at least three years, or the tumour was a non-melanoma skin tumour or in-situ cervix carcinoma.
3) Symptomatic or known Brain or leptomeningeal metastases.
4) Uncontrolled or severe cardiovascular disease including myocardial infarction within 6 months of enrollment, New York Heart Association (NYHA) Class III or IV heart failure (Attachment 10, NYHA Classification of Cardiac Disease), uncontrolled angina, clinically significant pericardial disease, or cardiac amyloidosis.
5) Patients may not have received more than 1 prior line of anti-neoplastic treatment for MPM.
6) Prior exposure to VELCADE.

Study design

Design

Study phase: 2

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-11-2006
Enrollment:	8
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Velcade
Generic name:	Bortezomib
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	07-09-2006
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO

Date:	17-10-2006
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
EudraCT	EUCTR2005-004420-39-NL
CCMO	NL12228.031.06