A Phase 3 Clinical Trial to evaluate the safety and efficacy of treatment with 2 mg intralesional Allovectin-7® compared to Dacarbazine (DTIC) or Temozolomide (TMZ) in subjects with recurrent metastatic melanoma

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The objective of the trial is to compare the efficacy and safety of treatment with Allovectin 7® versus treatment with DTIC or TMZ in subjects with recurrent metastatic melanoma. The results of the trial will be used to support registration of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON31643

Source
ToetsingOnline

Brief title
Allovectin-7® immunotherapy for metastatic melanoma (A.I.M.M.)

Condition

- Skin neoplasms malignant and unspecified

Synonym
disseminated melanoma, Stage 3, stage 4 melanoma

Research involving

Human

Sponsors and support

Primary sponsor: Vical Incorporated
Source(s) of monetary or material Support: Vical

Intervention

Keyword: Allovectin-7®, DTIC, Melanoma, Metastatic

Outcome measures

Primary outcome

To compare the overall response rate at *24 weeks after randomization in the

Allovectin-7® arm versus the control (DTIC/TMZ) arm.

Secondary outcome

First, to investigate the effect of Allovectin-7® in comparison to DTIC/ TMZ on

overall survival. Second: To investigate the safety/tolerability of

Allovectin-7® in comparison to DTIC/TMZ.

Study description

Background summary

The outlook for patients with advanced metastatic melanoma remains poor. Median survival ranges from 6*10 months, with few long-term survivors. Currently in the US, two single-agent products are indicated for first-line non-surgical treatment of metastatic melanoma: DTIC-Dome® (dacarbazine) and Proleukin® (aldesleukin). Both therapies are limited by high toxicity. An alternative therapy whereby efficacy and safety synchronize to provide the melanoma subject a palliative treatment is warranted.

Study objective

The objective of the trial is to compare the efficacy and safety of treatment with Allovectin 7® versus treatment with DTIC or TMZ in subjects with recurrent metastatic melanoma. The results of the trial will be used to support

registration of Allovectin 7® for marketing in the U.S., and may eventually be used to support marketing applications in the EU as well.

Study design

Phase 3, randomized (2:1), controlled, open-label, multi-center trial

Intervention

Treatment Arm: Allovectin-7® 2 mg intralesional injection into a single lesion weekly for six consecutive weeks, repeated beginning after each 8th week.
Control Arm: DTIC 1000 mg/m2 intravenous infusion over 60 minutes, repeated every 28 days Or TMZ 150 to 200 mg/m2 orally once daily for five consecutive days, repeated every 28 days.
Formal and complete disease assessments at pre-trial, Week 16, and at the end of every eight weeks for up to twelve months, then every twelve weeks for the second year, and for confirmation. If there is no protocol defined Progressive Disease (PD) and further treatment is likely to be tolerated, subjects will be encouraged to continue to the next cycle of treatment. An assessment for clinical progression or a need for Palliative Care will occur at Week 8.

Study burden and risks

Allovectin-7® has been given to over 700 subjects. Most side effects have been mild or moderate and the majority were due to pain or inflammation at the injection site. Other mild or moderate side effects have been chills, fatigue, nausea, general body aches, vitiligo (patchy loss of skin color), and fever.
There may not be any benefit for patients participating in the study.
Participation in this study may help cause remission of the disease and improve symptoms.

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

* Histologically confirmed recurrent metastatic melanoma, which may have received primary surgical resection, adjuvant therapy, and/or biotherapy
* At least one injectable lesion (cutaneous, subcutaneous, or nodal lesion) *1 cm2 and * 25 cm2
* Normal LDH
* ECOG performance status of 0 or 1

Exclusion criteria

* Surgery is deemed a curative option
* Prior cytotoxic chemotherapy
* Any lesion *100 cm2
* History of visceral metastasis, M1c, other than lung (M1b not excluded)

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):	28-04-2009
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	Genetic modified organism

Ethics review

Approved WMO Date:	12-03-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO Date:	23-05-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO Date:	15-08-2008
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2007-004120-21-NL
ClinicalTrials.gov	NCT00395070
CCMO	NL21254.000.08