A Randomized Controlled Phase II Clinical Trial with Intradermal IMO-2125 (Tilsotolimod) in pT3-4 cN0M0 Melanoma

Published: 04-06-2019
Last updated: 10-01-2025

This study has been transitioned to CTIS with ID 2023-509461-20-00 check the CTIS register for the current data. The primary objective is to investigate if IMO-2125 is capable of a) lowering the number of tumor positive SLN and b) inducing a loco-...

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

Summary

ID

NL-OMON52549

Source
ToetsingOnline

Brief title
Intrim 1 study

Condition

- Skin neoplasms malignant and unspecified

Synonym
Melanoma, skin cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Idera Pharmaceuticals, Inc,Idera Pharmaceuticals;Inc

Intervention

Keyword: Early stage melanoma, Immunotherapy, TLR-9 agonist

Outcome measures

Primary outcome

SLN tumor status 7 days after injection.

Secondary outcome

Loco-regional and systemic immune profile with emphasis on recruitment and/or

activation in the SLN of dendritic cell (DC), effector-T cell and Treg subsets,

and melanoma antigen-specific T cell responses in peripheral blood.

RFS and OS at 18 months, 24 months and 36 months after treatment.

Study description

Background summary

Currently, there is no widely used adjuvant treatment available to improve survival after surgical excision of a primary melanoma. We previously described loco-regional and systemic immune stimulation as well as favourable clinical outcomes in terms of sentinel lymph node (SLN) tumor status and recurrence-free survival (RFS) in patients with clinical stage I-II melanoma who received a low dose of the TLR-9 agonist CPG7909 (CpG-B ODN) intradermally at the excision site of the primary tumor prior to the SLN biopsy (SNB). We now investigate the clinical activity of a next-generation CpG ODN, IMO-2125, and its ability to induce loco-regional and systemic immune stimulation in pT3-4cN0M0 melanoma patients.

Study objective

This study has been transitioned to CTIS with ID 2023-509461-20-00 check the CTIS register for the current data.

The primary objective is to investigate if IMO-2125 is capable of a) lowering the number of tumor positive SLN and b) inducing a loco-regional and systemic immune response. The secondary objective is to investigate RFS and OS at 18

months, 24 months, 36 mnonths, 5 years en 10 jyears after treatment

Study design

A single center double-blind randomized and placebo-controlled Phase II clinical trial.

Intervention

Seven days before SNB, patients will receive an intradermal injection, directly adjacent to the excision site of the primary tumor, of 8mg IMO-2125 dissolved in 1 mL saline (0.9% sodium chloride) (n=107) or 1mL plain saline alone (placebo control n=107). 10 patients from each treatment arm will be enrolled in an immune monitoring sub study.

Study burden and risks

The burden associated with participation includes one intradermal injection at the VU university medical center. For the 20 patients in the immune monitoring sub study, 50 ml heparinized blood will be drawn at 5 time-points that will be planned together with standard treatment visits if possible but can result in 2 to 3 additional visits. The most common adverse events (AEs) seen with IMO-2125 are injection site reactions (ISR) and flu-like symptoms. In general, these reactions occur early and resolve within 48 hrs with non-specific measures. We do not expect to see any serious adverse events with IMO-2125 at this dose level. Potential benefits of IMO-2125 treatment in this trial may include SLN tumor clearance and a longer recurrence-free survival.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Patients must be willing and able to sign the informed consent and comply with the study protocol.
2. Must be >=18 years of age.
3. Histologically confirmed primary malignant melanoma cutis with a Breslow tumor depth >2.0 mm
4. WHO Performance Status <=1.
5. Women of childbearing potential (WOCBP) and fertile men must agree to use effective contraceptive methods from screening until at least 90 days after the IMO-2125 administration.

Exclusion criteria

1. Known hypersensitivity to any oligodeoxynucleotide.
2. Active autoimmune disease requiring disease-modifying therapy at the time of screening.
3. Pathologically confirmed loco-regional or distant metastasis.
4. Non-skin melanoma
5. Patients with another primary malignancy that has not been in remission for at least 3 years with the exception of non-melanoma skin cancer, curatively treated localized prostate cancer with non-detectable prostate-specific antigen, cervical carcinoma in situ on biopsy or a squamous intraepithelial lesion on Papanicolaou (Pap) smear, and thyroid cancer (except anaplastic).
6. Active systemic infections requiring antibiotics.
7. Women who are pregnant or breast-feeding.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-01-2020
Enrollment:	214
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	IMO-2125
Generic name:	Tilsotolimod

Ethics review

Approved WMO Date:	04-06-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-08-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	26-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-04-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	08-10-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-11-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EU-CTR	CTIS2023-509461-20-00
EudraCT	EUCTR2018-001992-19-NL
CCMO	NL66199.029.18