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Randomised study of dacarbazine versus dacarbazine plus G3139 (Bcl-2 Antisense Oligonucleotide, Genasense™) in patients with advanced malignant melanoma

Submission date
06/11/2002

Registration date
06/11/2002

Last Edited
08/02/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00016263

Protocol serial number
GM301

Study information

Scientific Title
Randomised study of dacarbazine versus dacarbazine plus G3139 (Bcl-2 Antisense Oligonucleotide, Genasense™) in patients with advanced malignant melanoma

Study objectives
To compare the effectiveness of dacarbazine with or without oblimersen (G3139) in treating patients who have advanced malignant melanoma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Malignant melanoma stages III and IV

Interventions
Patients will be randomly assigned to one of two groups:
1. Patients in group one will receive dacarbazine once every 3 weeks for up to eight courses in the absence of disease progression.
2. Patients in group two will receive 5 days of G3139 followed by an infusion of dacarbazine. Treatment may be repeated every 3 weeks for up to eight courses in the absence of disease progression.

After completion of the study patients will be evaluated every 2 months for a maximum of 2 years from the time of randomization.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Dacarbazine versus dacarbazine plus G3139 (Bcl-2 Antisense Oligonucleotide, Genasense™)

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. Measurable disease
2. No brain metastases
3. At least 4 weeks since biological therapy, radiation therapy or surgery
4. No previous chemotherapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2000

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
United States of America

Study participating centre
Genta Incorporated
Berkeley Heights
United States of America
NJ 07922

Sponsor information

Organisation
Genta Incorporated (USA)

Funder(s)

Funder type
Industry

Funder Name
Genta Incorporated (USA)

Funder Name
Aventis (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/10/2006	08/02/2019	Yes	No