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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	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/11/2002	**Overall study status** Completed	
Last Edited 08/02/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00016263

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2000

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
750

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)

Sponsor details
2 Connell Drive
Berkeley Heights
United States of America
NJ 07922

Sponsor type
Industry

Website
http://www.genta.com

Funder(s)

Funder type
Industry

Funder Name
Genta Incorporated (USA)

Funder Name
Aventis (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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