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Randomised phase III clinical trial in patients radically operated for stage III melanoma (American Joint Committee on Cancer [AJCC]): comparison between Interferon (IFN) alpha-2b (sec Eastern Cooperative Oncology Group [ECOG] 1684) versus intensified Interferon alpha-2b

Submission date
19/10/2005

Recruitment status
No longer recruiting

Registration date
21/10/2005

Overall study status
Completed

Last Edited
18/02/2008

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
IMI - Mel.A.

Study objectives
To verify if intensive intravenously IFN regimen is better than ECOG 1684 IFN regimen in patients with high risk melanoma (Stage III AJCC).

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Melanoma of cutaneous origin with regional lymph-node metastasis radically resected

Interventions
Dose-Dense/Dose-Intense arm: IFN alpha-2b 20 MU/m^2/day intravenously five days a week for four weeks, repeated for four times on weeks nine to 12, 17 to 20, 25 to 28

Standard arm: IFN alpha-2b 20 MU/m^2/day intravenously five days a week for four weeks followed by 10 MU/m^2 subcutaneously three times per week for 48 weeks.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Interferon alpha-2b

Primary outcome measure
Overall survival

Secondary outcome measures
1. Toxicity
2. Disease free survival

Overall study start date
15/11/1998

Completion date
15/11/2008

Eligibility

Key inclusion criteria
1. Primary melanoma of any tumour stage in presence of N1 regional lymph node metastases detected at elective or selective lymph node dissection with clinically not apparent regional lymph node metastases (designed CS1PS2, any TpN1M0)
2. Clinically apparent N1 regional lymph node involvement synchronous with primary melanoma of T1-4 (designed CS2PS2, any TcN1M0)
3. Regional lymph node recurrence at any interval after appropriate surgery for primary melanoma of any depth (designed CS2R, TxrN1M0)
4. ECOG performance status (PS) zero to one
5. Age 18 to 70
6. Absence of active medical or psychiatric troubles requiring medical or pharmacological interventions
7. Absence of thyroid or auto-immune pathology
8. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
328 patients

Key exclusion criteria
1. Patients with non-cutaneous primary melanoma
2. Clinical or pathological evidence of not completely resected melanoma or of lymph-node metastases
3. Clinical history of progressed neoplasia, except for the in situ carcinoma of the cervix and of radically treated basal carcinomas
4. Patients requiring a continuous treatment with steroids, non-steroid antiinflammatory drugs or other inhibitors of the prostaglandins synthesis, antihistaminic (cimetidine, ranitidine, famotidine and nazatidine) or other known immunomodulators
5. Patients with history of (ventricular or supraventricular) heart rhythm troubles needing treatment, or congestive heart failure (class New York Heart Association [NYHA] more than two)
6. Patients with organic brain syndrome or significant deterioration of the basal cognitive function or with any psychiatric trouble which may hinder the complete participation in the protocol or which may be exacerbated from the IFN therapy (e.g. depression)
7. Patients previously submitted to adjuvant therapy, chemotherapy, immunotherapy, including any perfusion therapy before surgery

Date of first enrolment
15/11/1998

Date of final enrolment
15/11/2008

Locations

Countries of recruitment
Italy

Study participating centre
Medical Oncology Unit
Venezia
Italy
30100

Sponsor information

Organisation

Italian Melanoma Intergroup - IMI (Italy)

Sponsor details
Istituto Oncologico Romagnolo
Corso Mazzini 65
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Italy
47100
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cor.epiclin@unipd.it

Sponsor type
Research organisation

Website
http://www.imi-online.it

Funder(s)

Funder type
Research organisation

Funder Name
Non-profit trial, partially supported by Italian Melanoma Intergroup (IMI)

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	27/02/2006		Yes	No