ISRCTN13456221 https://doi.org/10.1186/ISRCTN13456221

A Randomised Study of Observation versus Adjuvant Low Dose Extended Duration Interferon Alpha-2a in High Risk Resected Malignant Melanoma

Submission date
19/08/2002

Recruitment status
No longer recruiting

Registration date
19/08/2002

Overall study status
Completed

Last Edited
28/06/2012

Condition category
Cancer

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

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/aim-high-a-study-of-adjuvant-interferon-in-melanoma

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

Protocol serial number
AIM HIGH

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Skin cancer

Interventions
Patients are randomised to one of two treatment arms:
1. Arm A: Interferon alpha-2a 3MU three times per week until recurrence, or for 2 years.
2. Arm B: No further treatment.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Interferon Alpha-2a

Primary outcome(s)
Not provided at time of registration

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

Completion date
22/12/2000

Eligibility

Key inclusion criteria

1. Patients with histologically proven malignant melanoma and high risk of recurrent metastatic disease will be eligible for the present study. This will include patients with either:
a. Histologically proven metastatic melanoma in regional lymph nodes after therapeutic radical regional node dissection at initial presentation
b. Histologically proven metastatic melanoma in regional lymph nodes after therapeutic radical regional node dissection at subsequent presentation
c. Non-nodal superficial regional recurrence (local or in-transit disease)
d. Primary tumours 4 mm or more Breslow thickness without any other detectable focus of metastasis
2. Fit to receive interferon
3. Wound healed following surgery
4. Clinically disease-free
5. No history of other malignant disease, except previously cured early carcinoma of the cervix or skin
6. No previous biological therapy
7. Not on systemic steroids or other immunosuppressive therapy
8. Not pregnant, lactating or intending pregnancy during treatment
9. Less than 12 weeks since resection

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
22/12/2000

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Roche Products Limited (UK)

ROR
https://ror.org/024tgbv41

Funder(s)

Funder type
Industry

Funder Name
Roche Products Ltd

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	01/01/2004		Yes	No