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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	[_] Prospectively registered [_] Protocol
Registration date 19/08/2002	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 28/06/2012	**Condition category** Cancer	[_] 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 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
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

Age group
Not Specified

Sex
Not Specified

Target number of participants
674

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
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Roche Products Limited (UK)

Sponsor details
P.O. Box 8
Welwyn Garden City, Hertfordshire
United Kingdom
AL7 3AY

Sponsor type
Industry

Website
http://www.roche.com

ROR
https://ror.org/024tgbv41

Funder(s)

Funder type
Industry

Funder Name
Roche Products Ltd

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	01/01/2004		Yes	No