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The MoleMate™ UK Trial: The management of suspicious pigmented lesions in primary care

Submission date
20/12/2007

Recruitment status
No longer recruiting

Registration date
14/02/2008

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-a-new-way-for-family-doctors-to-check-moles-to-see-if-they-need-to-be-seen-by-a-specialist

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
The MoleMate™ UK Trial: The management of suspicious pigmented lesions in primary care

Study objectives

Suspicious pigmented lesions are a common presenting problem in general practice consultations, and while the majority are benign, a small minority are malignant melanomas. Over the last twenty-five years, the incidence of melanoma has increased more than for any other major cancer in the UK, to 8,000 new cases and 1,800 deaths annually. Studies suggest that general practitioners (GPs) are poor at differentiating melanomas from other pigmented lesions, and training GPs in melanoma diagnosis appears to have little significant effect on their performance. Alternative approaches are therefore required to increase the precision of assessment of pigmented skin lesions in primary care.

The MoleMate™ UK Trial, set in UK general practice, aims to test the hypothesis that the use of the MoleMate system will improve the effectiveness of management of suspicious pigmented lesions in primary care.

Please note that as of 04/01/10 the sources of funding for this trial have been updated. Biocompatibles UK Ltd will supply the MoleMate systems for the trial, in place of Astron Clinica.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Cambridgeshire 2 Research Ethics Committee on the 26th October 2007. REC Reference Number: 07/H0308/167

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Pigmented lesions/ diagnosis of melanoma

Interventions
The study aims to recruit 1,800 participants from 15 general practices (intervention group 900; control group 900) over a trial period of 16 months per practice.

Patients who are eligible and agree to participate will be randomised to either the control group, where the lesion will be assessed by eye according to current 'best practice', or the intervention group, where the lesion will be assessed by eye according to current 'best practice' followed by an assessment of the lesion using the MoleMate system. A clinical decision will then be made and the participant either reassured or referred to dermatology.

All participants will be asked to complete an exit questionnaire within one week of their appointment and a follow-up questionnaire after 3 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The proportion of referred pigmented lesions that are monitored or biopsied from the intervention group compared with the proportion of referred pigmented lesions that are monitored or biopsied from the control group. This will reflect the extent to which use of the MoleMate system in primary care increases the diagnostic accuracy and appropriateness of referrals to secondary care.

Key secondary outcome(s))
1. Assessment of participant satisfaction and anxiety at one week and three months after the consultation in general practice
2. Comparison of the diagnostic performance of clinicians with the MoleMate system and without
3. Assessment of clinician learning when using the MoleMate system
4. Assessment of clinician confidence in the MoleMate system
5. Examination of the association between the 'Index of Suspicion' scale and the seven-point checklist, and their predictiveness of lesion outcomes
6. Economic analysis of using the MoleMate system in primary care
7. Creation of a cohort of participants from the trial who will have melanoma-specific diagnosis and mortality over 5-years survival outcomes assessed

Completion date
30/06/2010

Eligibility

Key inclusion criteria
1. 18 years or over
2. Attending a GP or practice nurse appointment at a study general practice
3. The patient or practitioner describes a pigmented lesion, although the lesion need not be the presenting symptom

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment

1297

Key exclusion criteria
1. Patients with a pigmented lesion which is immediately diagnosed as benign and the patient reassured
2. Patients who do not give their consent or are not able to understand the consent process
3. Patients felt unsuitable by their GP due to other on-going physical or psychological conditions such as cognitive impairment, serious illness

Date of first enrolment
01/01/2008

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
General Practice and Primary Care Research Unit
Cambridge
United Kingdom
CB2 0SR

Sponsor information

Organisation
University of Cambridge and Cambridgeshire NHS Primary Care Trust (UK)

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Government

Funder Name

The NHS National Institute for Health Research (NIHR): School for Primary Care Research (main funder) (UK)

Funder Name
Biocompatibles UK Limited have supplied the MoleMate systems for the trial.

Funder Name
Cambridge R & D Consortium - Cambridgeshire Primary Care Trust transitional funding is providing service support for the additional consultations in general practices (UK)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	31/08/2010		Yes	No
Results article	results	04/07/2012		Yes	No
Protocol article	protocol	11/05/2010		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			26/10/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes