

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

Submission date 20/12/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/02/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2022	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> 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>

Study website

<http://www.medschl.cam.ac.uk/gppcru/Projects/MoleMate/>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Diagnostic

Participant information sheet

Participant information sheet: <http://www.medschl.cam.ac.uk/gppcru/Projects/MoleMate/downloads.htm>

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/01/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1,800 participants from 15 general practices

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**

England

United Kingdom

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)

Sponsor details

Research Services Division
University of Cambridge
16 Mill Lane
Cambridge
England
United Kingdom
CB2 1SB

Sponsor type

Hospital/treatment centre

Website

<http://www.rsd.cam.ac.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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	11/05/2010		Yes	No
Results article	results	31/08/2010		Yes	No
Results article	results	04/07/2012		Yes	No
Plain English results			26/10/2022	No	Yes