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A study in primary care of nomela® to exclude melanoma

Submission date 15/01/2018	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol
Registration date 23/01/2018	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 01/04/2019	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

Melanoma is the most important skin cancer as it can spread and may kill. The numbers of new cases have been increasing substantially in recent years despite public health warnings and advice. The large majority of pigmented moles of the skin are benign but concerns about the possibility of malignancy place a substantial load on primary and secondary health services. Only about 1 in 20 moles referred to specialist dermatologists are shown to be melanoma. The nomela® test is sophisticated software analysing a digital photograph to give an immediate result to provide reassurance to doctor and patient. Approximately 60% of pigmented moles that would have been referred are shown by the test as having no evidence of melanoma. The nomela® test is not a diagnostic test for melanoma but is a screening test which may help the general practitioner or primary care nurse. The aim of this study is to demonstrate that the nomela® test can screen out a significant proportion of pigmented cutaneous lesions as not melanoma from those being referred from primary care to specialist review.

Who can participate?

Adults aged 16 and older who have skin lesions.

What does the study involve?

Participants are asked to participate by the general practitioner/practice nurse if they have presented with a pigmented mole which it has then been decided needs a specialist opinion. Participants are asked to provide written consent after being provided with an information sheet. The doctor or nurse then performs the nomela® test using a dedicated iPad by taking a photograph of the mole. It takes 1 -3 minutes to perform the test. Although the test result is immediately available it is not used in the study to influence the decision to refer. This ends the participation of the patient in the study. The diagnosis made subsequently by the specialist, with or without microscopic examination of any mole removed, is used to check the performance of the nomela® test.

What are the possible benefits and risks of participating?

There are no direct benefits or risks with participating.

Where is the study run from?
This study takes place in NHS Lanarkshire Health and Social Care Partnerships (UK) and Sentinel Health (UK).

When is the study starting and how long is it expected to run for?
April 2017 to October 2018

Who is funding the study?
Moletest (Scotland) Ltd. (UK)

Who is the main contact?
Dr Peter Freedman (Scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Peter Freedman

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
nomela® C5

Study information

Scientific Title
A study in primary care of nomela®, an imaging analysis technology, to exclude cutaneous melanoma

Study objectives

The aim of this study is to demonstrate that the nomela® test can screen out a significant proportion of pigmented cutaneous lesions as not melanoma from those being referred from primary care to specialist review.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Open single-step non-randomised performance evaluation

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Cutaneous melanoma

Interventions
Patients being seen in primary care on whom referral to specialist review has been decided are asked to participate in this study if they satisfy the inclusion criteria and with lesions which satisfy the inclusion criteria.

Participants are given Participant Information Sheets and Consent Forms (with opportunitiy to ask questions, by GP or practice nurse)

After written consent is obtained, the nomela® test is performed using the designated iOS device provided for the study (an iPad on which all other functions have been disabled.

The time to take the nomela® test (identification, location, checking of image) should be less than 3 minutes (with experience 1 minute).

Although the test result is immediately available the decision to refer will not be changed.

This is the end of participation by the patient in the study.

The patient is subsequently seen by the respective specialist dermatologist and managed on routine basis which may include mole removal again on routine basis.

The consent includes access and use of the specialist diagnosis including if performed the histopathology diagnosis.

Intervention Type
Device

Primary outcome measure
Sensitivity and specificity is mesaured using statistic analysis.

Secondary outcome measures
Testing the electronic reporting mechanism by nomela® to NHS records.

Overall study start date
13/04/2017

Completion date
31/10/2018

Reason abandoned (if study stopped)
Research Ethics Committee approval not applied for.

Eligibility

Key inclusion criteria
1. Patients presenting to primary care for assessment of suspicious pigmented skin lesions AND being referred to Dermatology Departments for specialist review on routine clinical decision.
2. Age 16 years and over. No gender discrimination.

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
1000

Key exclusion criteria

1. Other skin conditions considered by the primary care physician not to be pigmenyted moles
2. Patients unable or unwilling to give informed consent.
3. Age less than 16 years.
4. Lesions not suitable for the nomela® test

Date of first enrolment
01/03/2018

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
NHS Lanarkshire Health and Social Care Partnerships
United Kingdom
ML3 0AA

Study participating centre
Sentinel Health
United Kingdom
PL6 8BU

Sponsor information

Organisation
Moletest (Scotland) Ltd.

Sponsor details
1 Exchange Crescent, Conference Square
Edinburgh
United Kingdom
EH3 8UL

Sponsor type

Industry

Funder(s)

Funder type
Industry

Funder Name
Moletest (Scotland) Ltd.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/10/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Peter Freedman (peter.freedman@moletest-scotland.com.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v3		01/04/2019	No	Yes