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Testing of nomela® on images confirmed as melanoma

Submission date 15/01/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 18/01/2018	**Overall study status** Completed	
Last Edited 23/04/2021	**Condition category** Cancer	

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 (non-cancerous) but concerns about the possibility of malignancy (cancerous) place a large 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. This study aims to provide a significant increase in the number of images of melanoma to support the reference ranges which are used in the software screening process.

Who can participate?
Participants are contacted only to obtain wider consent for this research. The images of their lesions have been taken previously as this in part of the routine care. Participant's previous consent did not cover the scope of this study. The Pathology department creates lists of provisional cases of confirmed melanoma using the CHI and transfers the list to Medical Illustration who establishes whether they have images of the skin lesions and checks quality. If satisfactory the clinical researcher/dermatologists contacts the patients with a covering letter, participant information sheet and a consent form. After consent is received, the images are tested using the the nomela® test as though they were freshly acquired. The sensitivity of the nomela® test is assessed.

What does the study involve?
There is no direct involvement with participants. Previous images are reviewed using the technology in order for the sensitivity to be measured against reference ranges.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
University Hospital Monklands (UK)

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

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

Who is the main contact?
Dr Peter Freedman

Contact information

Type(s)
Scientific

Contact name
Dr Peter Freedman

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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number
242101

ClinicalTrials.gov number

Secondary identifying numbers
IRAS 242101, Nomela® C7

Study information

Scientific Title
Testing of nomela® on images of skin lesions confirmed as cutaneous melanoma

Study objectives

The aim of this study is to increase confidence in the ranges used by nomela® as a screening test to exclude melanoma in suspicious pigmented moles by evaluating historic images of lesions confirmed as cutaneous melanoma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland REC 5, 24/04/2018

Study design
Retrospective non-randomised cohort study single study performance evaluation

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files

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

Interventions
There is no direct involvement of participants. In effect there is no enrolment nor participation except that participants are being asked to widen the scope of consent so that the use of images of the skin lesions which were taken in the course of routine clinical practice in the period defined (and which predates the performance of the study) encompasses this specific research. The "duration of observation" is an instant and there is no follow-up. There is no feedback as clinical care is not affected.

Participants are contacted only to obtain wider consent for this research. The images of their lesions already exists as this in part of the routinue clinical pathway that the NHS Lanarkshire has used for several years. The previous consent did not cover the scope of theis research. The Pathology department creates lists of provisional cases of confirmed melanoma using the CHI and transfers the list to Medical Illustration who establishes whether they have images of the skin lesions and checks quality. If satisfactory the clinical researcher/dermatologists contacts the patients with a covering letter, participant information sheet and a consent form. After consent is received, the images are tested using the the nomela® test as though they were freshly acquired.

Intervention Type

Device

Primary outcome measure
Sensitivity is measured against reference ranges defined in previous range-finding study (Moletest004) note that specificity will not be available in this study.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
31/05/2017

Completion date
30/11/2018

Eligibility

Key inclusion criteria
1. Age 16 years and over
2. Having a confirmed diagnosis of cutaneous melanoma in NHS Lanarkshire

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
At least 80

Total final enrolment
98

Key exclusion criteria
1. Unable or unwilling to give informed consent
2. Aged less than 16 years

Date of first enrolment
02/08/2018

Date of final enrolment
31/10/2018

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University Hospital Monklands
Department of Pathology
Airdrie
United Kingdom
ML6 0JS

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

Current publication and dissemination plan as of 23/04/2021:
Planned publication in a high-impact peer reviewed journal. 2020 results presented at the British Association of Dermatologists Annual Meeting https://static1.squarespace.com/static/5de661ce046bfb288316094f/t/5f6dcb979683b943de1ba336/1601031069793/BAD_POSTER.pdf.

Intention to publish date
30/11/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the dataset is to confirm ranges used by the nomela® test. The information is held by Moletest (Scotland) Ltd.

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

IPD sharing statement:
The datasets generated during and/or analysed during the current study are not expected to be made available as the dataset is to confirm ranges used by the nomela® test. The information is held by Moletest (Scotland) Ltd.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2	16/01/2018	02/02/2018	No	Yes