

# Testing of nomela® on images confirmed as melanoma

<b>Submission date</b> 15/01/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/04/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 (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 is 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 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

**ORCID ID**  
<http://orcid.org/0000-0002-2282-0646>

**Contact details**  
Moletest (Scotland) Ltd  
24 Westover Road (2nd floor)  
Bournemouth  
United Kingdom  
BH1 2BZ

## 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 routine clinical pathway that the NHS Lanarkshire has used for several years. The previous consent did not cover the scope of this 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](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?
<a href="#">Participant information sheet</a>	version v2	16/01/2018	02/02/2018	No	Yes