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Testing nomela® on moles (C8)

Submission date 04/11/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 06/11/2019	**Overall study status** Suspended	[_] Statistical analysis plan [X] Results
Last Edited 08/01/2025	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Most skin moles are not serious but an important small number are serious (melanoma). The load on health services from moles with a suspicion of malignancy is substantial yet many moles referred to hospital are considered benign on inspection by the specialist. However, some moles require a skin biopsy to clarify the diagnosis. This study will check the performance of nomela®, a photographic image analysis test using tablet software technology, which aims to assist in the exclusion of melanoma. If nomela® is shown to work well it would be used to reduce the need for referral for a skin biopsy.

Who can participate?
Patients with a pigmented mole which the specialist has decided on routine clinical grounds to have removed for a specialist pathology opinion

What does the study involve?
When the specialist has decided to arrange for a biopsy of the mole or for the mole to be removed the routine practice is to have photographs taken of the mole(s) by the Media Studio photographers. The only extra activity over the routine is that participants have nomela® test photographs taken of their mole in this clinic by the nurse using a specially prepared iPad: this lasts a few minutes. Their routine care is not affected.

What are the possible benefits and risks of participating?
There will be no direct benefit to participants at present. However, if the nomela® test is found to be fit for purpose then specialist dermatologists/plastic surgeons and general practitioners will support its wider use. There is very little risk associated with taking part in the study. Whether patients take part or not in the study, the specialist has considered that biopsy or removal of the mole is needed. This will be explained separately and a separate consent will be requested. The risk of exposure of personal data is minimised as follows. The patient’s hospital number is only shown on the electronic consent form. This is immediately transferred securely from the device to a dedicated research NHS email which is only available to the specialist doctor and the dedicated clinical research team. No personal or test information of any kind is kept on the nomela® device on completion of the test and its transfer. The hospital number is encrypted securely on the Moletest server only for linkage to the diagnosis of the skin biopsy by the clinical research team but cannot be discovered by anyone other than the specialist doctor and dedicated clinical research team. The results of this study will be published in suitable

medical journals and presentations may be made at relevant medical conferences. Under no circumstances will patients' names or other personal details be revealed. Participants will be able to request a summary of the results of the study from the Dermatology Department, Addenbrooke's Hospital if they wish.

Where is the study run from?
Cambridge University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2019 to September 2022

Who is funding the study?
Moletest (Scotland) Ltd

Who is the main contact?
1. Dr Nigel Burrows
2. Dr Ed Rytina

Contact information

Type(s)
Scientific

Contact name
Dr Peter Freedman

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
254451

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
nomela®C8, IRAS 254451, CPMS 40826

Study information

Scientific Title
Testing nomela® on suspicious pigmented naevi (moles): a hospital-based study

Acronym
nomela®C8

Study objectives
1. To measure the performance of the nomela® test as a risk calculator for melanoma in pigmented skin lesions of patients referred by specialists for biopsy/excision and histopathology.
2. To demonstrate that the nomela® test provides at least 95+/- 2 % sensitivity for not-melanoma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/04/2019, East of England - Cambridge Central Research Ethics Committee (Royal Standard Place, Nottingham, NG1 6FS, UK; Tel: +44 (0)207 104 8101; Email: NRESCommittee.EastofEngland-CambridgeCentral@nhs.net), REC ref: 19/EE/0041

Study design
Open single-step non-randomized performance evaluation of a medical device

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Melanoma in pigmented cutaneous moles

Interventions
The nomela® test, a technology for capturing digital images of skin lesions and making an analysis by signal-processing. nomela® test output to be compared with histopathology result.
Total duration of observation: 5 minutes for the single nomela® test.
No determination of clinical decision.
No follow-up.
Histology diagnosis collected within 12 weeks.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
The nomela® test

Primary outcome measure
Sensitivity (95% CI) of the nomela® test for not-melanoma. Measured at a single timepoint.

Secondary outcome measures
The proportion (95% CI) of lesions that the nomela® test finds as having 'no evidence of melanoma'. Measured at a single timepoint.

Overall study start date
03/05/2018

Completion date
15/09/2022

Eligibility

Key inclusion criteria
Patients referred on routine clinical decision by the Dermatology/Plastic Surgery Departments for biopsy/excision biopsy and histopathology of suspicious pigmented skin lesions

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200 completed nomela® tests of pigmented skin lesions confirmed by histopathology as melanoma (all types)

Total final enrolment
1489

Key exclusion criteria
1. Other skin conditions not considered to be pigmented moles
2. Lesions not considered suitable for nomela®: pigmented moles smaller than 5mm diameter; moles obscured by hair, scar or tattoos; moles in the mouth, eyelid, nailbed, genital and perianal areas; ulcerated lesions; non-pigmented moles which may be the amelanotic form of melanoma;

lesions likely to be basal cell carcinoma, squamous cell carcinoma, Merkel cell tumours, lymphoma, metastatic carcinoma
3. Patients unable or unwilling to give informed consent
4. Patients aged less than 16 years

Date of first enrolment
09/09/2019

Date of final enrolment
20/06/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Dermatology
Box 46
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Moletest (Scotland) Ltd

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Sponsor type
Industry

Website

www.moletest-scotland.com

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
15/09/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Bruce Murray, Technical Director (bruce.murray@moletest-scotland.com). Type of data: the nomela® test analysis result (text) and histology result (diagnosis). When the data will become available and for how long: at overall trial end; not specified, ?3 years. By what access criteria data will be shared including with whom: not specified. For what types of analyses: not specified. By what mechanism: online after email enquiry. Whether consent from participants was obtained: consent for research use of anonymised data obtained from participants. Comments on data anonymisation: hash-one-way encryption hospital number means not available except to clinical team; the number is expunged from the dataset on entry of histology diagnosis category i.e before overall trial end.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2.0	28/03/2019	08/11/2019	No	Yes
Protocol file	version v3.1	05/04/2019	08/11/2019	No	No
HRA research summary			28/06/2023	No	No
Results article		11/11/2024	08/01/2025	Yes	No