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Poor correlation between spectrophotometric intracutaneous analysis and histopathology in melanoma and non-melanoma lesions

Submission date 27/01/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/02/2010	**Overall study status** Completed	
Last Edited 28/08/2013	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
VGSKAS-11928, VGFOUSKB-8498, VGFOUSKB-7934, VGFOUREG-8263

Study information

Scientific Title
Comparison of diagnostic information from spectrophotometric intracutaneous analysis and histopathology in melanoma and non-melanoma lesions: an observational study

Study objectives
The aim of this study was to evaluate the diagnostic information given by the SIAscope (Spectrophotometric Intracutaneous Analysis [SIA]) applied to suspicious malignant melanomas by comparison with histopathological findings.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee of Gothenburg (Regionala etikprövningsnämnden i Göteborg) approved on the 23/02/2004 (ref: 018-04)

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Melanoma

Interventions
The included lesions were SIAscopically imaged and documented before excision and histopathological preparation. A specially developed preparatory and documentary procedure was undertaken to find the areas of interest in the histological sections thus obtaining accurate topographic comparisons to the SIAgraphs.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
1. SIAgraphs were evaluated for features indicating melanoma and the following were calculated:
1.1. Sensitivity
1.2. Specificity
1.3. Positive Predictive Value (PPV)
1.4. Negative Predictive Value (NPV)
2. Topographical comparisons between SIAscopy findings and histopathology were made. Level of agreement was assessed by Kappa statistics.

Secondary outcome measures
N/A

Overall study start date
01/09/2004

Completion date
31/12/2007

Eligibility

Key inclusion criteria
Lesions clinically suspicious for melanoma and showing positive SIAscopic findings during routine investigations

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
Aged under 18 years

Date of first enrolment
01/09/2004

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Sweden

Study participating centre
Skaraborg Hospital
Skövde
Sweden
541 85

Sponsor information

Organisation
Research and Development council, Västra Götaland (Forskning och Utveckling, Västra Götaland [Fou VGreg]) (Sweden)

Sponsor details
Hälso- och sjukvårdsavd Regionkansliet,
Regionens Hus
Göteborg
Sweden
405 44

Sponsor type
University/education

Website
http://www.fou.nu/is/vgregion

ROR
https://ror.org/00a4x6777

Funder(s)

Funder type
Research organisation

Funder Name
Research and Development council, Västra Götaland (Forskning och Utveckling, Västra Götaland [Fou VGreg]) (Sweden) (ref: VGFOUSKB-8498, VGFOUSKB-7934)

Funder Name
Research and Development council, Skaraborg (Forskning och Utveckling, Skaraborg [FoU Skaraborg]) (Sweden)

Funder Name
Research and Development council, Skaraborgs Sjukhus (Forskning och Utveckling, Skaraborgs Sjukhus [FoU SkaS]) (Sweden) (ref: VGSKAS-11928)

Funder Name
Skaraborg institute (Sweden)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2013		Yes	No