

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

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| Submission date 27/01/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 18/02/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 28/08/2013 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)

Primary study design

Observational

Study design

Observational cohort study

Study type(s)

Diagnostic

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(s)

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.

Key secondary outcome(s)

N/A

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

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

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 |