

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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)

## **Study design**

Observational cohort study

## **Primary study design**

Observational

## **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?
<a href="#">Results article</a>	results	01/06/2013		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes