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Comparison of traditional and fluorescence detection of non-melanoma skin cancer

Submission date
24/10/2011

Recruitment status
No longer recruiting

Registration date
07/11/2011

Overall study status
Completed

Last Edited
05/11/2012

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Non melanoma skin cancer (NMSC) is the most common form of skin cancer and has been shown to affect more than one in six in a population of Caucasian males in the north of England. Although the risk of spreading to other organs and loss of life is relatively low compared to melanoma skin cancer, lesions of NMSC need to be removed as they will otherwise keep on growing unchecked. Early treatment prevents avoidable deaths and complications and treatment of less progressed lesions usually is less burdensome to the patient and can avoid repeated treatments.
The problem which limits the number of lesions treated at an early stage is that the condition does not have any symptoms. That is, early lesions do not itch, present little or no scaling or redness and are difficult to notice. As a result, many lesions of NMSC go unnoticed by the patient or GP.
There is a new method for identifying NMSC called fluorescence detection. Fluorescence is phenomenon that some compounds emit light (i.e. glow) when they are illuminated with a certain kind of light. Some compounds are either more or less prominent in NMSC fluoresce, which can be used to identify NMSC, i.e. detect them based on their fluorescence properties.
In this study we us a compound called 5-aminolevulinic acid (5-ALA) which is applied to the skin and after the application, one can find the NMSC by looking for those areas of the skin that show relatively high levels of fluorescence. This should allow a specialist to be able to find NMSC before they are visible to the naked eye. This study aims to find out if fluorescence detection is more accurate than the traditional clinical inspection at finding NMSC.

Who can participate?
Any person being suspected of having a NMSC with Fitzpatrick skin type I, II or III.

What does the study involve?
Participants have a standardized clinical inspection. A trained doctor examines the skin in a systematic manner in order to find symptoms associated with NMSC. During the examination the doctor looks at your skin to see if there are any reddish lesions, or if there is some scaling. In addition, the doctor feels if there are some irregularities such as scaling or bumps. Every time the doctor finds an area that might contain a NMSC, it is noted on a form for later investigation. Following the inspection, fluorescence detection is performed. This consists of the application

of a spray containing 0.5% 5-aminolevulinic acid for 2.5 hours, following which fluorescence measurements are performed with a specially developed camera and system. Those areas which based on the fluorescence detection or the clinical inspection are deemed to be suspicious of containing a NMSC are further investigated, identified and if necessary treated.

What are the possible benefits and risks of participating?
Benefits of the study include identifying NMSC earlier so that patients can be treated earlier. There is a risk of some minor irritation of the skin (some red spots and some swelling) if it is exposed to intense sunlight after the investigation, which can last for three hours. The spray used in this study contains fats. As a result, skin will be a bit greasy. Participants will need to have a shower or take a bath before going to bed, otherwise some minor skin irritation can occur. If the skin gets irritated then there is no need for concern. The symptoms will disappear within a week without further treatment.

Where is the study run from?
ZBC Multicare, the Netherlands

When is study starting and how long is it expected to run for?
The study started in late 2011 and ended in early 2012.

Who is funding the project?
ZBC Multicare

Who is the main contact?
Nick van der Beek
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Contact information

Type(s)
Scientific

Contact name
Mr Nick van der Beek

Contact details
Hoge Naarderweg 7 H
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1217AB

Additional identifiers

Protocol serial number
MC 2011/10

Study information

Scientific Title

Observer blinded intra-patient direct comparison of the accuracy of classical method and auto-fluorescence normalized liposomal encapsulated 5-aminolevulinic acid induced protoporphyrin IX (PpIX) fluorescence detection method of detecting non-melanoma skin cancer

Study objectives
Auto-fluorescence normalized liposomal encapsulated 5-aminolevulinic acid induced protoporphyrin IX fluorescence detection has a higher sensitivity and specificity than 10 minute visual inspection and palpation in a general clinical setting when detecting non-melanoma skin cancers (NMSC)

As of 04/01/2012, anticipated end date of trial was corrected from 31/01/2012 to 03/01/2012.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ZBC Multicare Medical Ethical Committee, 28 September 2011, ref: 20011/10

Primary study design
Interventional

Study design
Prospective observer blinded intra-patient direct comparison study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Non-melanoma skin cancer

Interventions
Visual inspection and palpation for the detection of non-melanoma skin cancer versus auto-fluorescence normalized liposomal encapsulated 5-aminolevulinic induced protoporphyrin IX fluorescence detection of non-melanoma skin cancer

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. False positives, false negatives, true positives and true negatives are recorded for both methods
2. The true and false negatives are calculated using the combined locations of true and false positives of both methods. Based on these sensitivity and specificity of both methods are calculated.

Key secondary outcome(s)
No secondary outcome measures

Completion date
03/01/2012

Eligibility

Key inclusion criteria
1. Male and female aged 40 and over
2. History of NMSC
3. Being referred to a dermatologist for a NMSC check-up

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Use of a peeling agent
2. Use of 5-fluorouracil (5-FU)
3. Skin type IV or higher
4. Skin type III with tanning less than two months prior to the participation
5. Recent tanning
6. Porphyria
7. Epilepsy
8. Inflammatory disease (e.g. psoriasis, acne)
9. Excessive hair on chest or face

Date of first enrolment
01/11/2011

Date of final enrolment
03/01/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Hoge Naarderweg 7 H
Hilversum

Netherlands
1217AB

Sponsor information

Organisation
ZBC Multicare (Netherlands)

ROR
https://ror.org/0325z9a60

Funder(s)

Funder type
Industry

Funder Name
ZBC Multicare (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration