

Three non-invasive Treatment Options for superficial basal cell carcinoma: PDT vs. imiquimod vs. 5-fluorouracil

Published: 26-07-2007

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This research has the goal to determine which treatment is the most effective treatment in terms of prevention of treatment failure, in costs and has the patients preference when comparing PDT, Imiquimod and 5FU.

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|------------------------------|--|
| Ethical review | Approved WMO |
| Status | Recruiting |
| Health condition type | Skin neoplasms malignant and unspecified |
| Study type | Interventional |

Summary

ID

NL-OMON31670

Source

ToetsingOnline

Brief title

Treatment of sBCC

Condition

- Skin neoplasms malignant and unspecified

Synonym

basal cell carcinoma, skin cancer

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Zon NW

Intervention

Keyword: 5-fluorouracil, basal cell carcinoma, imiquimod, PDT

Outcome measures

Primary outcome

Outcome measures: The primary outcome measure is treatment failure within 12 months after treatment.

Secondary outcome

Secondary outcome measures are degree of pain experienced during treatment, compliance with treatment, side effects of treatment, patient preferences and health care costs.

Study description

Background summary

Skin cancer is the most common cancer in Caucasians, and a basal cell carcinoma (BCC) being the most common skin cancer with 36.000 new tumours per year, and its incidence is still rising. In the past it has been a disease of the elderly patient but as a consequence of recreational sun exposure and tanning beds, more young patients develop a skin cancer as well. There are different subtypes of BCC and most subtypes are treated by surgical excision. Nowadays, non-invasive techniques (Photodynamic therapy (PDT), imiquimod and 5-fluorouracil (5FU)) are common practice to treat superficial BCC (sBCC). Because of these techniques treatment by an excision can be avoided with the possibility of complications and scar formation. Which treatment the patient will receive, does not rely on evidence based medicine but on the preference of the physician; there are no data regarding cost-effectiveness or patients preference.

Study objective

This research has the goal to determine which treatment is the most effective treatment in terms of prevention of treatment failure, in costs and has the patients preference when comparing PDT, Imiquimod and 5FU.

Study design

Study design: a randomized controlled multi-centre study

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Intervention

Intervention: PDT versus imiquimod versus 5-fluorouracil

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Study burden and risks

not applicable

Contacts

Public

Academisch Medisch Centrum

P. Debyelaan 25
6202 AZ Maastricht
NL

Scientific

Academisch Medisch Centrum

P. Debyelaan 25
6202 AZ Maastricht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

All patients with a primary (no previous treatment) histopathologically confirmed diagnosis of one or more sBCCs aged between 18 and 80 years old.

Exclusion criteria

Patients using immunosuppressive drugs, patients with genetic skin cancer disorders, location in the H-zone or the hairy head, earlier treatments at the same site and pregnancy.

Study design

Design

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|------------------|-------------------------------|
| Study phase: | 4 |
| Study type: | Interventional |
| Masking: | Single blinded (masking used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

Recruitment

| | |
|---------------------------|------------|
| NL | |
| Recruitment status: | Recruiting |
| Start date (anticipated): | 26-03-2008 |
| Enrollment: | 600 |
| Type: | Actual |

Medical products/devices used

| | |
|---------------|-----------------------|
| Product type: | Medicine |
| Brand name: | Aldara creme |
| Generic name: | imiquimod 5% creme |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |

| | |
|---------------|-------------------------|
| Brand name: | Efudix creme |
| Generic name: | 5 Fluorouracil creme |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | Metvix |
| Generic name: | methyl amino levulinate |
| Registration: | Yes - NL intended use |

Ethics review

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|--------------------|---|
| Approved WMO | |
| Date: | 26-07-2007 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

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| Approved WMO | |
| Date: | 29-10-2007 |
| Application type: | First submission |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

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| Approved WMO | |
| Date: | 24-01-2008 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

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| Approved WMO | |
| Date: | 28-01-2008 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

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|--------------------|---|
| Approved WMO | |
| Date: | 07-04-2008 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

Approved WMO

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|--------------------|---|
| Date: | 19-05-2008 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO | |
| Date: | 26-05-2008 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO | |
| Date: | 02-06-2008 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO | |
| Date: | 04-07-2008 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO | |
| Date: | 26-10-2009 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

EudraCT

CCMO

ID

EUCTR2007-002776-33-NL

NL17969.068.07