

A randomized clinical trial of excision versus photodynamic therapy in the treatment of Bowen's disease

Published: 04-01-2007

Last updated: 10-05-2024

Excision versus PDT in the treatment of Bowen's disease. What's the best therapy on behalf of recurrence rate, cosmetic outcome and cost-utility.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON30319

Source

ToetsingOnline

Brief title

Morbus Bowen: excision versus photodynamic therapie

Condition

- Skin neoplasms malignant and unspecified
- Skin and subcutaneous tissue therapeutic procedures

Synonym

Intraepithelial squamous cell carcinoma, skincancer

Research involving

Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: Ziekenhuis

Intervention

Keyword: Bowen's disease, Excision, Photodynamic therapie, Treatment

Outcome measures

Primary outcome

Recurrence rate

Secondary outcome

Cosmetic outcome

Cost-utility

Study description

Background summary

A randomised clinical trial of excision versus photodynamic therapy in the treatment of Bowen's disease

Bowen's disease is also called intraepithelial squamous cell carcinoma. It's a form of skincancer restricted to the epidermis. There is however a risk of progressing to invasive squamous cell carcinoma and metastasizing. The risk of getting invasive lies around 3 %. There are many different treatment modalities for the diseasevoor de aandoening, for example excision, photodynamic therapy (PDT), 5-Fluorouracil, curettage, electrocoagulation and laser. All treatments show the sam recurrence rates of 5-15 %. There are however few randomised prospective clinical trials, which can give a wrong presentation. In our study we want to compare the two most used therapies in the treatment of Bowen's disease, excision and PDT, within recurrence rate, cosmetic outcome and cost-utility.

Study objective

Excision versus PDT in the tratment of Bowen's disease. What's the best therapy on behalve of recurrence rate, cosmetic outcome and cost-utility.

Study design

Prospective randomised clinical trial: excision versus PDT

- Questionnaires about general health and functioning, treatment(experience) and cosmetic outcome.
- Clinical follow-up to detect recurrences

Intervention

Excision or PDT

Study burden and risks

Not applicable

Contacts

Public

Catharina-ziekenhuis

Michelangelolaan 2
5623 EJ Eindhoven
Nederland

Scientific

Catharina-ziekenhuis

Michelangelolaan 2
5623 EJ Eindhoven
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Histopathologic proven Bowen's disease scalp, face, torso, arms and legs

Age > 18 years

Informed consent

Exclusion criteria

Recurrent Bowen's disease

Anogenital or subungual Bowen's disease

Other skin malignancies in the same area

Porphyria

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 25-05-2007

Enrollment: 224

Type: Actual

Ethics review

Approved WMO

Date: 04-01-2007

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO	
Date:	13-03-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	ID
EudraCT	EUCTR2006-006430-18-NL
CCMO	NL15192.060.06