

Three non-invasive treatment options of superficial basal cell carcinoma

Submission date 01/04/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/04/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/03/2019	Condition category Cancer	☐ 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

Clinical Trials Information System (CTIS)
2007-002776-33

Study information

Scientific Title
Three non-invasive treatment options of superficial basal cell carcinoma: photodynamic therapy (PDT) vs imiquimod vs 5-fluorouracil: TTOP-sBCC trial

Acronym
TTOP-sBCC

Study objectives

There is no significant difference in recurrence rate and cosmetic outcome between the three treatment options. There will be a significant difference in cost effectiveness, PDT is expected to be much more expensive than the other two treatment options.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethics Committee of the Maastricht University, 29/10/2007

Primary study design

Interventional

Study design

Randomised single-blind multi-centre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Superficial basal cell carcinoma

Interventions

Arm 1: Photodynamic therapy with Metvix®, 2 times 37 J/cm² with one week between the two sessions. Lamp used: Omnilux PDT™, Waldmann PDT™ or Aktilite PDT™ (Galderma).

Arm 2: Imiquimod (Aldara®): 5/7 days, once a day for 6 weeks

Arm 3: 5-fluorouracil (Efudix®): 7/7 days, two times a day for 4 weeks

Follow up: 3 months-12 months (-2 years-3 years-4 years-5 years)

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Imiquimod, 5-fluorouracil.

Primary outcome(s)

1. Clearance rate 3 months after the end of interventions
2. Recurrence rate 1 year after the end of interventions

Key secondary outcome(s)

1. Cost effectiveness
2. Patient preference, assessed by a questionnaire 1.5 years after the start of the study
3. Compliance, assessed by a questionnaire based on items of the Brief Medication Questionnaire (ref: Svarstad BL et al. The Brief Medication Questionnaire: a tool for screening patient adherence and barriers to adherence. Patient educ couns. 1999 Jun; 37(2): 113-24).
4. Side effects (pain), assessed using a questionnaire during treatment

5. Cosmetic outcome at 3 months and 1 year, assessed by both patient and one blinded medical doctor using the Patient and Observer scale (ref: Draaijers LJ et al. The patient and observer scale assessment scale: a reliable and feasible tool for scar evaluation. Plast Reconstr Surg. 2004 Jun; 113(7): 1960-5) and a 5-point scale.

Completion date

01/03/2011

Eligibility

Key inclusion criteria

1. Primary histologically proven superficial basal cell carcinoma of the skin
2. Age 18-80 years
3. Both men and women

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Not Specified

Total final enrolment

601

Key exclusion criteria

1. Genetic skin malignancies
2. Tumour location: peri-ocular, auricular, nasal, hairy scalp
3. Pregnancy
4. Treatment with systemic immunosuppression therapy

Date of first enrolment

01/03/2008

Date of final enrolment

01/03/2011

Locations

Countries of recruitment

Netherlands

Study participating centre

P.Debyelaan 25

Maastricht

Netherlands

6202 AZ

Sponsor information

Organisation

The Netherlands Organisation for Health Research and Development (ZonMw)

ROR

<https://ror.org/01yaj9a77>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

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	1-year results	01/06/2013		Yes	No
Results article	sub-group analysis results	01/03/2015		Yes	No
Results article	5-year results	01/03/2018	14/03/2019	Yes	No

