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Three non-invasive treatment options of superficial basal cell carcinoma

Submission date	Recruitment status	[_] Prospectively registered
01/04/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/03/2019	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised single-blind multi-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Superficial basal cell carcinoma

Interventions
Arm 1: Photodynamic therapy with Metvix®, 2 times 37 J/cm^2 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 measure
1. Clearance rate 3 months after the end of interventions
2. Recurrence rate 1 year after the end of interventions

Secondary outcome measures
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 scare assessment scale: a reliable and feasible tool for scar evaluation. Plast Reconstr Surg. 2004 Jun; 113(7): 1960-5) and a 5-point scale.

Overall study start date
01/03/2008

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Not Specified

Target number of participants

600 patients

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)

Sponsor details
Postbus 93 245
Den Haag
Netherlands
2509 AE

Sponsor type
Research organisation

Website
http://www.zonmw.nl

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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