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Surgical excision versus Mohs micrographic surgery for primary and recurrent basal cell carcinoma of the face

Submission date	Recruitment status	[_] Prospectively registered
15/10/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/10/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/01/2015	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
OG 99-030

Study information

Scientific Title
Examining the (cost-) effectiveness of Mohs micrographic surgery versus surgical excision in the treatment of primary and recurrent basal cell carcinoma: a prospective randomised study

Acronym
MP

Study objectives
Mohs micrographic surgery (MMS) is superior to surgical excision in recurrence rate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of the Maastricht University on the 20th October 1999

Study design
Randomised controlled multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Primary or first or second recurrent basal cell carcinoma

Interventions
Arm 1: Mohs micrographic surgery -
Tumours were excised with a margin of 3 mm under an angle of 45 degrees. The complete resection margins of the excised material were investigated histopathologically on horizontal frozen section slides. In case of positive resection margins, the procedure was repeated, until total clearance was obtained. The duration of the procedure was dependent of the number of mohs stages. Primary and secondary outcome measures were measured after 5 years follow-up.

Arm 2: surgical excision -
Tumours were excised with a margin of 3 mm under an angle of 90 degrees. The

histolopathological examination was performed on vertical slides. The duration of the procedure was approximately 45 minutes per treatment. Primary and secondary outcome measures were measured after 5 years follow-up.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Recurrence of carcinoma after 5 years follow-up

Secondary outcome measures
1. Determinants of failure after 5 years of follow-up, tested with Cox regression analysis
2. Cost-effectiveness after 5 years of follow-up an incremental cost-effectiveness ratio was calculated, all personal and material costs of both treatments that have been made during procedures and follow-up were calculated by multiplying volumes of use with the cost per unit

Overall study start date
01/11/1999

Completion date
01/02/2007

Eligibility

Key inclusion criteria
1. Primary or first or second recurrent basal cell carcinoma
2. Aged 18 years or older, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
408 (primary basal cell carcinoma) and 204 (recurrent basal cell carcinoma)

Key exclusion criteria
Expected life-duration of less than 3 years

Date of first enrolment

01/11/1999

Date of final enrolment
01/02/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
P. Debyelaan 25
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Sponsor information

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

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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) (ref: OG 99-30)

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	results:	01/11/2004		Yes	No
Results article	results	01/11/2014		Yes	No