

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

<b>Submission date</b> 15/10/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/10/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/01/2015	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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 histopathological 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(s)**

Recurrence of carcinoma after 5 years follow-up

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

Maastricht

Netherlands

6202 AZ

# Sponsor information

## Organisation

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

## 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

## 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?
<a href="#">Results article</a>	results:	01/11/2004		Yes	No
<a href="#">Results article</a>	results	01/11/2014		Yes	No