

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Nicole Kelleners-Smeets

Contact details
P. Debyelaan 25
Maastricht
Netherlands
6202 AZ
-
n.kelleners.smeets@mumc.nl

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

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 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

Maastricht

Netherlands

6202 AZ

Sponsor information

Organisation

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

Sponsor details

P.O. Box 93245

Den Haag

Netherlands

2509 AE

-

info@zonmw.nl

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