Postoperative interstitial high-dose-rate (HDR) brachytherapy in the treatment of therapy-resistant keloids. Long-term results of AMC cohort

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4.OBJECTIVETo analyse the outcomes, results and complications, of the keloid treatment with excision followed by immediate adjuvant HDR brachytherapy at the AMC between July 2007 and October 2014.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cutaneous neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON42479

Source
ToetsingOnline

Brief title
Postoperative brachytherapy for keloids. Outcomes AMC

Condition

- Cutaneous neoplasms benign

Synonym
Keloid, scar-benign-tumour

Research involving
Human

Sponsors and support

Primary sponsor: Radiotherapie - AMC

Source(s) of monetary or material Support: geen. Reiskosten reimbursement zal door de afdeling radiotherapie zelf betaald worden

Intervention

Keyword: Brachytherapy, Keloids, Radiotherapy

Outcome measures

Primary outcome

7.TREATMENT / INTERVENTION

For every keloid a data distraction form will be filled in (see appendix I). It includes patient and keloid characteristics, which will be extracted from the patients* records.

The outcome measurements will be evaluated at the moment of the assessment consultation.

8.METHODS

8.1.Study procedure

All consecutive keloids treated with excision followed by HDR brachytherapy at the AMC are subject of inclusion, thus 60 consecutive patients with a follow up longer than 12 months.

Patients will be invited to undergo a clinical assessment at the plastic and reconstructive surgery outpatient clinic. This will be done by means of an invitation letter.

No extra imaging, blood test or other intervention will be performed.

During this interview, for every keloid, a distraction data form (Appendix I) will be filled in. It includes patient characteristics, keloid characteristics

en outcome measurements.

In case the patients are unable to come but willing to participate in the study they can do it in the form of a call interview. In the informed consent form, the patient can fill in a desired date and time frame for the call interview. During the call interview the required information for items E and F of the distraction form will be collected by asking the patient.

During the first month of the project all the clinical assessments will be performed. During the second month the information will be analysed.

The results of the study will be presented at national and international meetings and submitted as a paper for a peer reviewed scientific medical journal.

8.2.Study parameters/endpoints

The first end-point will be the recurrence rate defined as a growing, pruritic, nodular scar.[11] A subjective scar evaluation will be performed by the patient and an independent medical doctor using the validated Patient and Observer Scar Assessment Scale (POSAS) as a descriptive measure to record the postoperative scar (Appendix II).

The secondary end point will be toxicity [dehiscence of the wound, infection, chronic wound, skin ulceration, hyperpigmentation and hypopigmentation].

8.3.Withdrawal of individual subjects

Patients can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a patient

from the study for urgent medical reasons.

Secondary outcome

The secondary end point will be toxicity [dehiscence of the wound, infection,

chronic wound, skin ulceration, hyperpigmentation and hypopigmentation].

Study description

Background summary

3.INTRODUCTION AND RATIONALE

Keloids are benign fibrous dermal tumours characterized by excessive deposition of extracellular matrix due to excessive collagen synthesis and decreased collagen degradation [1], extending often beyond the site of the initial injury. [2] It impairs the quality of life of patients due to pruritus, aching, itching and cosmetic disfigurement. [3] Hypertrophic scars on the contrary do not extend outside the wound area [2,4] and after a few months they tend to regress without further treatment. [4]The incidence of keloids is hard to determine, although it is known that in Black and Hispanic people it lies between 4.5% and 16% with peaks during puberty and pregnancy. [5] In 50-80% of the keloids excision alone results in recurrence [6], being an elevation of the scar outside the initial wound. [7] This high recurrence rate has led to several therapy options, such as interferon [1], pressure therapy, surgery, laser therapy, cryotherapy, intralesional corticosteroid injection, 5FU-injections, topical imiquimod [8], radiotherapy or a combination of these therapies. [9] The combination of surgery and immediate postoperative radiotherapy is considered the most effective for severe therapy-resistant keloids. [10] Though this combination has been used for nearly a century [1], the optimal radiation scheme and the way of administering this radiation, either external beam radiotherapy or brachytherapy, is still unknown. [6]

A dose-effect relationship for keloids with the biologically effective dose (BED) as dose unit has been reported. [6] The optimal treatment is probably an irradiation scheme resulting in a BED value of at least 30Gy which can be obtained with, for instance, a single acute dose of 13 Gy, two fractions of 8 Gy or three fractions of 6 Gy [with High-Dose-Rate (HDR)] or a single dose of 27 Gy at Low-Dose-Rate. The radiation treatment should be administered within 2 days after surgery.

In 2007 the results of adjuvant treatment based on external beam radiotherapy of the AMC cohort were reported .[4] Patients received 12Gy in 3-4 fractions

with superficial 250-kV electron beam irradiation prescribed at a 25- or 50-cm source-to-skin distance using a 1-mm copper filter, starting within 24 hours after surgical excision. Unfortunately, the results were disappointing with a higher rate of recurrence in comparison to the literature partly being explained by the long follow-up and the strict inclusion criteria.

Since then at the Academic Medical Center (AMC) in Amsterdam the adjuvant treatment after excision of therapy-resistant keloids includes the use of HDR brachytherapy which permits to increase the BED and allows to administer the dose in one single fraction, with a prescribed dose of 13Gy at 4-7mm from the source, within the 2 hours after extralesional excision of the keloid.

In 2012 we reported the preliminary long term results based on a retrospective study of 24 consecutive patients with 28 keloids with promising results (World Brachytherapy Congress 2012).

At the present time with a longer follow up and higher number of patients we would like to assess the results in terms of recurrence and toxicity of our cohort.

Study objective

4.OBJECTIVE

To analyse the outcomes, results and complications, of the keloid treatment with excision followed by immediate adjuvant HDR brachytherapy at the AMC between July 2007 and October 2014.

Study design

5.STUDY DESIGN

Retrospective observational cohort study with prospective collection of updated data.

Study burden and risks

nvt

Contacts

Public
Selecteer

Meibergdreef 9
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NL
Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients treated with excision and adjuvant brachytherapy for a keloid at the Academic Medical Center between July 2007 and October 2014. The cohort consist of 60 patients with 70 keloids

Exclusion criteria

Inability or unwillingness of the patient to provide informed consent or legally incompetent/incapacitated to do so

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2015
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	26-10-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL55213.018.15