The management of actinic keratosis in transplant recipients.

No registrations found.

Ethical review	Not applicable
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25323

Source
Nationaal Trial Register

Brief title
5-FU_IMQ_PDT

Health condition

patients' preference, transplant patients, actinic keratosis, imiquimod, 5-Fluorouracil, Photodynamic therapy.

Sponsors and support

Primary sponsor: Erasmus MC, department dermatology
Source(s) of monetary or material Support: Galderma, France

Intervention

Outcome measures

Primary outcome

Patients preference.

Secondary outcome

1. Cosmetic outcome;

2. Tolerability;

3. Efficacy.

Study description

Background summary

Objective:

To determine patient’s preference between MAL-PDT and 5-FU and IMQ next to study treatment efficacy, safety and investigators preference of treatments.

Study design:

A randomized monocentric controlled single-blinded study.

Study population:

Solid organ transplant recipients aged 18 years and older which have > 5 mild to moderate AKs on the dorsa of both hands.

Intervention:

2 groups of 30 patients: Methyl aminolevulinate PDT (MAL-PDT) versus 5-FU and Methyl aminolevulinate PDT (MAL-PDT) versus IMQ.

Main study parameters/endpoints:

Primary parameter will be patient’s preference between treatment with MAL-PDT, IMQ or 5-FU.
Secondary parameters are efficacy, safety (clinical skin appearance, adverse event, photo toxicity and wound healing time) and investigators preference.

Study objective

N/A

Study design

After inclusion (day 1), patients will be seen at:

Day 1: Start IMQ or 5-FU on one hand and MAL-PDT on the other hand;

Week 1: 2nd session PDT on the hand randomized in MAL-PDT treatment;

Week 3: A conference call to make sure a good compliance is achieved;

Week 12: Evaluations and end of the study.

Intervention

Left/right MAL-PDT and left/right respectively topical treatment.

Contacts

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Eligibility criteria

Inclusion criteria

1. Adults (above the age of 18 years old);

2. Solid organ transplant recipients (heart, lung, kidney and liver) under stable immunosuppressive treatment since 6 months;

3. Informed consent signed;

4. More than 5 mild to moderate AK (clinical diagnosis) on both dorsal hands with symmetrical involvement in term of severity and number.

Exclusion criteria

1. A treatment for AK on the dorsal hand in the last 3 months;

2. Taking oral retinoid within 4 weeks before enrolment;

3. Pregnancy or breastfeeding during the study;

4. A proven allergy for one of the used products in the study;

5. Other skin disease including invasive SCC on the dorsa of the hand; in doubt histology will be performed.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-07-2013
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL3772
NTR-old	NTR3930
CCMO	NL39975.078.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A