Prevention of lymphedema by therapeutic elastic compression hoses; treatment efficacy.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22336

Source
NTR

Brief title
PROTECT

Health condition

inguinal lymph node dissection
lymphedema
lymfoedeem
oppervlakkige liesklierdissectie
therapeutisch elastische kousen
compression hoses

Sponsors and support

Primary sponsor: The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital (dpt of physiotherapy)
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

Incidence of lymphedema (survival without lymphedema).

Secondary outcome

1. Early surgical complications (wound breakdown, lymphocele formation, wound infection);

2. Genital oedema;

3. Health related quality of life;

4. Body image;

5. Ccompliance to usage of the hose;

6. Use of professional homecare;

7. Lymphedema requiring treatment.

Study description

Background summary

Patients after inguinal lymphnode dissection will be followed up to 12 months post-surgery. Patients in hose group will wear a class II therapeutic compression hose in addition to patient education as provided to no-hose group. Survival analysis (cox regression) will be used to estimate treatment effect.

Study objective

H0: incidence of lymphedema in hose-group equals non-hose group;

H1: incidence of lymphedema in hose group does not equal non-hose group.

Study design

N/A

Intervention

Therapeutic elastic compression hose for a period of 6 months, in addition to standard regimen of early ambulation and patient education.

Contacts

Public
The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital, Dpt of Physiotherapy
M.M. Stuiver
Plesmanlaan 121
Amsterdam 1066 CX
The Netherlands
+31 20-5122586
Scientific
The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital, Dpt of Physiotherapy
M.M. Stuiver
Plesmanlaan 121
Amsterdam 1066 CX
The Netherlands
+31 20-5122586

Eligibility criteria

Inclusion criteria

1. 18 years or older;

2. Inguinal lymphnode dissection because of metastases of melanoma or urogenital tumour.

Exclusion criteria

1. Deep venous thrombosis;

2. Manifest lymphedema or episodes of lymphedema in the past;

3. Isolated limb perfusion treatment;

4. Oedema as a result of venous insufficiency;

5. Psychiatric disorders;

6. Lacking basic proficiency in dutch.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2006
Enrollment:	80
Type:	Actual

Ethics review

Positive opinion

Date:	27-03-2007
Application type:	First submission

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	NL917
NTR-old	NTR941
Other	: N/A
ISRCTN	ISRCTN23026635

Study results