

# Prevention Of lymphoedema by Therapeutic Elastic Compression hoses: Treatment efficacy

<b>Submission date</b> 02/05/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/05/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/09/2021	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
NL917 (NTR941)

# Study information

## Scientific Title

Prevention Of lymphoedema by Therapeutic Elastic Compression hoses: Treatment efficacy

## Acronym

PROTECT

## Study objectives

H0: incidence of lymphoedema in hose-group equals non-hose group.

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

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approval received from the Medical Ethical Committee of The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital on the 4th September 2006 (ref: PTC06.1170/MO6PRO).

## Study design

Randomised, active controlled, parallel group, multicentre trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Compression hoses, lymphoedema, inguinal lymph node dissection

## Interventions

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

## Intervention Type

Procedure/Surgery

## Phase

Not Specified

## Primary outcome measure

Incidence of lymphoedema (survival without lymphoedema); surface measurements are used to calculate limb volume to establish the diagnosis of lymphoedema at T0, T1, T2, T3, T4 and T5.

### **Secondary outcome measures**

1. Early surgical complications (wound breakdown, lymphocele formation, wound infection), measured at T2
2. Genital oedema, measured at T0, T1, T2, T3, T4 and T5
3. Health related quality of life, measured at T0, T4 and T5
4. Body image, measured at T4 and T5
5. Compliance to usage of the hose, measured at T2, T3 and T4
6. Use of professional homecare
7. Lymphoedema requiring treatment

T0: day of admittance

T1: day of dismissal

T2: first outpatient visit two months after dismissal

T3: second outpatient visit four months after dismissal

T4: third outpatient visit six months after dismissal

T5: fourth outpatient visit 12 months after dismissal

### **Overall study start date**

01/10/2006

### **Completion date**

31/12/2007

## **Eligibility**

### **Key inclusion criteria**

1. 18 years or older
2. Inguinal lymph node dissection because of metastases of melanoma or urogenital tumour

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Not Specified

### **Target number of participants**

80

### **Key exclusion criteria**

1. Deep venous thrombosis
2. Manifest lymphoedema or episodes of lymphoedema 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
7. Skin diseases of the leg

**Date of first enrolment**

01/10/2006

**Date of final enrolment**

31/12/2007

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

**The Netherlands Cancer Institute**

Amsterdam

Netherlands

1066 CX

## **Sponsor information**

**Organisation**

Netherlands Cancer Institute (NKI) (The Netherlands)

**Sponsor details**

Antoni van Leeuwenhoek Hospital (AVL)

Plesmanlaan 121

Amsterdam

Netherlands

1066 CX

**Sponsor type**

Research organisation

**Website**

<http://www.nki.nl/>

**ROR**

<https://ror.org/03xqtf034>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Netherlands Cancer Institute (NKI) (The Netherlands)

# 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