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PRevention Of lymphoedema by Therapeutic Elastic Compression hoses: Treatment efficacy

Submission date 02/05/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 02/05/2007	**Overall study status** Completed	
Last Edited 23/09/2021	**Condition category** Surgery	

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 Comittee 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
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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