# TIN FOIL FOR PREVENTION OF FANTOM LIMB PAIN AFTER A LOWER LEG AMPUTATION, CAUSED BY COMPLICATED VASCULAR DISEASE: a randomised cross-over study

Published: 23-04-2007
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application of tin foil on an amputated leg deminishes fantoom pain

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Arteriosclerosis, stenosis, vascular insufficiency and necrosis |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON31254

**Source**
ToetsingOnline

**Brief title**
Tin foil and fantom pain

### Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

**Synonym**
fantom pain, tin foil

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Onze Lieve Vrouwe Gasthuis

**Source(s) of monetary or material Support:** vakgroep chirurgie

## Intervention

**Keyword:** aluminium, amputation, fantom pain, tin foil

## Outcome measures

### Primary outcome

fantom pain (VAS score)

### Secondary outcome

wound pain (VAS score)

infection rate

# Study description

### Background summary

Their is anecdotical evidence that tin foil might decrease fantom pain after a lower limp amputation.

### Study objective

application of tin foil on an amputated leg deminishes fantoom pain

### Study design

randomised cross over design

### Intervention

tin foil on a amputation stump

### Study burden and risks

no burden

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

- lower limb amputation (upper or lower leg)
- critical vascular disease
- informed consent
- primary closure of the wound

## Exclusion criteria

- no primary closure of the wound (infection)

# Study design

## Design

| | |
|---|---|
| Study phase: | 3 |
| Study type: | Interventional |
| Intervention model: | Crossover |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Placebo |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-04-2007 |
| Enrollment: | 60 |
| Type: | Anticipated |

# Ethics review

Approved WMO

| | |
|---|---|
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

# 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 | NL16655.067.07 |