De Afhang Studie

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20011

Source
NTR

Brief title
DANGLE

Health condition

Lower leg reconstruction
Free flap

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

The primary objective is to assess whether a no dangling protocol is non-inferior to a dangling protocol in terms of proportion of patients who experienced partial flaps loss which did not
require another free lap procedure at six months after surgery.

Secondary outcome

- We hypothesize that there will be no difference in major complications at 6 months.

- We would like to objectify the gaseous changes within the free flap during the dangling protocol in a selective group of patients.

- We will measure the physical functions at 3 and 6 months with the PROMIS and EQ-5D questionnaires.

- We hypothesize that there is no difference in the number of patients experiencing one or more minor complications at three and six months post operative.

- Investigate if there is a difference in the length of hospital stay between the two groups.

Study description

Background summary

Within the field of plastic surgery free tissue transfer is common practice. In knee and lower leg defects due to trauma,
oncological resection or chronic infection adequate soft tissue coverage of bony structures is imminent. In case of insufficient
bony coverage a muscle or fasciocutaneous (skin and fat) free tissue transplantation is performed. This is a microsurgical
operation in which a part of the body is transplanted to the defect. However, there is a great diversity in the postoperative care
for patients with a lower leg reconstructions. The frequency and way of post-operative monitoring, wrapping of the lower leg,
total hospital stay, and the gradual increase of gravitational forces on the free flap (dangling) are all critical protocols in the
postoperative care. Although, there is internationally no evidence based consensus supporting the use of some of these
protocols. With this randomized controlled trial we would like to further investigate the need for dangling protocols in these
patients.

Worldwide there are multiple variations of dangling protocols. The starting point, frequency, and duration of dependency vary
widely; where some start the dangling protocol as early as on the second postoperative day, others wait until the fourth
postoperative week (1–3). The remainders report to not use dangling as a standard procedure at all, or only in selected
cases. When applied, the dangling sessions are prescribed once up to six or more times a day, with a duration ranging from

one up to 21 minutes per session. In general the dangling protocol is performed in a hospital setting. Consequently, patient
discharge plans are highly variable ranging from discharge at postoperative day four (when no dangling protocol is applied) to
discharge in postoperative week three, with higher medical costs and patient discomfort as a result.
The best available evidence concerning an early start of the dangling procedure comes from the articles of Jokuszies et al.
(2013) and Neubert et al. (2015). These are the only two known randomized controlled trials available. They show that the
combined wrapping and dangling procedure can safely be started at postoperative day three, in patients treated with a variety of
free flaps. However it must be noted that the patients included in this study are for the most part the same group of patients.
Furthermore, the number of patients in these studies were small: 31 and 49, for Jokuszies and Neubert respectively,
resulting in an underpowered study. A larger randomized controlled trial is necessary to be able to amend the post-operative
care in clinical settings.

Kolbenschlag et al. conducted a prospective cohort study and used the same dangling schedule. However, they did not start
their dangling procedure until postoperative day 6 and furthermore, they differentiated between the different types of free flaps
and medical conditions of patients.

Since there is limited evidence available in the literature supporting a dangling protocol further research is required.

Study objective

We hypothesize that there is no difference in the number of patients experiencing partial flap loss at six months post operative.

Study design

1 week postoperative start study

12-15 days postoperative

6 weeks postoperative

3 months postoperative

6 months postoperative

Intervention

Dangling of the lower leg vs. no dangling of the lower leg in patients treated with a free flap for lower leg reconstruction.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

- Male or female

- Age between 18 and 99 years old

- Lower leg defect in need for a free flap reconstruction

Exclusion criteria

- Age under 18 years

- Co-morbidities that prevent the patient from being able to undergo a dangling protocol

- Insufficient Dutch language skills to understand the study

- Mentally incompetent, Patients that are unable to give informed consent

- Reconstruction with 2 or more free flaps

- In case of a re-intervention the patient will be excluded from the study only if the arterial and/or venous anastomosis required a
redo.

- In case the patient is getting a secondary free flap due to partial or total free flap necrosis of the primary one.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-10-2018
Enrollment:	130
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-10-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50700
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7329
NTR-old	NTR7545
CCMO	NL63146.041.17
OMON	NL-OMON50700

Study results