The Dangle Study

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Primary objective parameter: 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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON50700

Source
ToetsingOnline

Brief title
DANGLE

Condition

- Fractures
- Soft tissue therapeutic procedures

Synonym
Dangling of the free flap. Gravity training of the free flap.

Research involving
Human

Sponsors and support

Primary sponsor: Plastisch chirurgie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dangle, Flap, Leg, Reconstruction

Outcome measures

Primary outcome

Primary objective parameter: 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. We defined complete flap necrosis, partial flap necrosis (if a revision surgery with a second free flap is necessary) and lung embolia as major complications. Screening for lung embolia will only be performed if there is a clinical suspection for a lung embolia. Partial flap loss is defined as minor if no secondary free flap is needed or major if a secondary free flap was needed. Wound dehiscence, wound infection, failure of skin graft take on the free flap, and hematoma for which a surgical exploration was needed were defined as the minor complications.

Secondary outcome

Secondary objective parameters:

- 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, 1 year, 1,5 years and 2 years with the PROMIS, EQ-5D and VAS-score 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.

- Investigate infection rates and osseous union rates with a follow up of two

years based on the patients* medical files.

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 (1), or only in selected cases (2). 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 (3), 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) (4) and Neubert et al. (2015) (5). 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 (4-5), 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 (6). 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

Primary objective parameter: 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. We defined complete flap necrosis, partial flap necrosis (if a revision surgery with a second free flap is necessary) and lung embolia as major complications. Screening for lung embolia will only be performed if there is a clinical suspection for a lung embolia. Partial flap loss is defined as minor if no secondary free flap is needed or major if a secondary free flap was needed. Wound dehiscence, wound infection, failure of skin graft take on the free flap, and hematoma for which a surgical exploration was needed were defined as the minor complications.

Secondary objective parameters:
- 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, 1 year, 1,5 years and 2 years with the PROMIS, EQ-5D and VAS-score 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.
- Investigate infection rates and osseous union rates with a follow up of two years based on the patients* medical files.

Study design

The design of this study is a randomized controlled multicenter trial. The

study will take place in three Dutch hospitals: UMC Utrecht, Erasmus MC Rotterdam and UMC Groningen. The study will end when 130 patients are included with a maximum of three years. Within this study there will be two patient groups. The patients will be randomized by a computer system to group A or B. Patients in group A will start at postoperative day 7 with the dangling protocol. Patients in group B are allowed to dangle for an unlimited time starting at postoperative day 7. Blood tests will be performed in all patients randomized in group A at the UMC Utrecht. All patients will be invited for two short (PROMIS, EQ-5D and VAS) online questionnaires at 3 and 6 months, 1 year, 1,5 years and 2 years post operative.

*

Intervention

- No dangling protocol
- Patients randomized in group A at the UMC Utrecht will undergo blood tests with the use of a Point Of Care Testing (POCT) device. Point of Care Testing is a technique that only needs a drop of blood and subsequently analyze this drop of blood for pO2, pCo2 and PH levels. This test will not influence the overall result of the study. The test is performed to monitor the gaseous changes within the free flap during dangling. Within the UMC Utrecht this a commonly performed test to monitor patients during anesthesia.

Study burden and risks

Based on the current literature there are no known increased risks involved with the participation in this study. The hypostasised beneficial effect is that patients in group B might have a shorter hospital stay. Patients randomised to group A in the UMC Utrecht will undergo blood tests during the dangling protocol. All patients will be invited to fill out two short online questionnaires at 3 and 6 months, 1 year, 1,5 years and 2 years postoperative. The estimated total time needed for filling out these questionnaires is 25 minutes.

Contacts

Public
Selecteer

Heidelberglaan 101

Utrecht 3584 CX
NL
Scientific
Selecteer

Heidelberglaan 101
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Male or female
- Age between 16 and 99 years old
- Lower leg defect in need for a free flap reconstruction

Exclusion criteria

- Age under 16 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 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:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-10-2018
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO Date:	11-07-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	17-10-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-10-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	10-01-2019
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	15-02-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-07-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-11-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-03-2023
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20011
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63146.041.17
OMON	NL-OMON20011