

# The effect of locally applied platelet-rich fibrin on donor sites and recipient sites after split-thickness skin transplantation

<b>Submission date</b> 09/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/02/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/07/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## 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

(KF) 01286728

## Study information

### Scientific Title

### Acronym

The Donor Study

### Study objectives

Platelet-rich fibrin shortens wound healing time and improves aesthetic outcome

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Yes, 19/09/2005, ref: (KF)01286728

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Quality of life

### Participant information sheet

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

Chronic leg ulcer

### Interventions

Split-thickness skin transplantation

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome measure

Epithelialization on day five and nine post-operatively

## **Secondary outcome measures**

1. Clinical appearance
2. Histological evaluation
3. Transepidermal Water Loss (TEWL)
4. Erythema
5. Microbiology
6. Incidence of infection
7. Unwanted side effects
8. Temperature difference between treated patients and control group patients

## **Overall study start date**

01/01/2006

## **Completion date**

01/04/2007

# **Eligibility**

## **Key inclusion criteria**

1. Patients undergoing surgery for chronic leg ulcer
2. Aged over 18 years
3. Written informed consent, the patient is expected to be able to complete the study
4. Donor site area from 2 x (3 cm x 5 cm) to 2 x (7.6 cm x 15 cm)

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Both

## **Target number of participants**

20

## **Key exclusion criteria**

1. Non-Danish speaking
2. Dementia
3. Pregnant or breastfeeding women
4. Patients treated with 10 mg of steroid or more daily
5. Patients that have received thrombocyte-inhibiting medicine less than four days before surgery
6. Patients not suited for general or spinal anaesthesia
7. Patients whose donor site has been used as a donor site before
8. Patients with skin diseases or pathological changes in the skin, including infection

**Date of first enrolment**

01/01/2006

**Date of final enrolment**

01/04/2007

## **Locations**

**Countries of recruitment**

Denmark

**Study participating centre**

**Bispebjerg Hospital**

2400 Kobenhavn NV

Denmark

2400

## **Sponsor information**

**Organisation**

Vivolution A/S (Denmark)

**Sponsor details**

Blokken 45

3460 Birkerød

Denmark

3460

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**Sponsor type**

Industry

**Website**

<http://www.vivolution.com>

**ROR**

<https://ror.org/010knjd35>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Vivolution A/S (Denmark)

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2008		Yes	No
<a href="#">Results article</a>	results	01/05/2013		Yes	No