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

Submission date 09/01/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/02/2006	**Overall study status** Completed	
Last Edited 24/07/2014	**Condition category** Circulatory System	

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
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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?
Results article	results	01/11/2008		Yes	No
Results article	results	01/05/2013		Yes	No