

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
Registration date 17/02/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/07/2014	Condition category Circulatory System	☐ 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

Protocol serial number
(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

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Chronic leg ulcer

Interventions

Split-thickness skin transplantation

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Epithelialization on day five and nine post-operatively

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Vivolution A/S (Denmark)

Results and Publications

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