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Tissue engineered autologous grafting versus standard care in the treatment of diabetic foot ulcers

Submission date	Recruitment status	[ ] Prospectively registered
24/06/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/08/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/08/2009	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

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
CT/240/248/98-03

Study information

Scientific Title
Evaluation of the efficacy and safety of autologous grafts of fibroblasts and keratinocytes grown on scaffolds composed of HYAFF 11, a derivative of hyaluronic acid, in the treatment of diabetic foot ulcers: a randomised, controlled, multicentre trial

Study objectives
The study compared the efficacy and adverse event profile of autologous tissue engineered grafts (Hyalograft 3D™ autograft and Laserskin® autograft) versus standard care (paraffin gauze) in the local treatment of diabetic foot ulcers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Università Cattolica del Sacro Cuore - Facoltà di Medicina e Chirurgia (Agostino Gemelli) approved on the 22nd February 1999 (ref: Prot.Dg P37/C.E. [A. 48]). The study received the favourable opinion by the Ethic Committees of all the 7 centres involved. All other centres will seek ethics approval before recruiting participants.

Study design
Randomised controlled multicentre clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Doriana Senigaglia at dsenigaglia@fidiapharma.it to request a patient information sheet

Health condition(s) or problem(s) studied
Diabetic foot ulcer

Interventions
The study protocol provided a first treatment phase with the grafting of Hyalograft 3D™ autograft (autologous graft of fibroblasts grown on a HYAFF scaffold) followed, a fortnight later, by the grafting of Laserskin® autograft (autologous graft of keratinocytes grwon on a HYAFF scaffold). Single or double grafts of each products were allowed at the investigator's discretion.

The control group was treated with the paraffin gauze Jelonet on direct contact with the wound.

All the patients used an appropriate off-loading device (plantar ulcers) or therapeutic shoes (dorsal ulcers).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hyalograft 3D™ autograft, Laserskin® autograft

Primary outcome measure
Rate of healing at 12 and 20 weeks (complete healing was defined as complete re-epithelialisation of the wound).

Secondary outcome measures
Evaluated at 12 weeks:
1. Mean healing time
2. Time to achieve 50% area reduction
3. Weekly percentage of ulcer area reduction

Registered during the entire course of the study; a specific analysis was performed at 12 weeks and at the 18 months follow-up:
4. Number and severity of adverse events

In order to enhance the quality of the observation, the tolerability of the treatment was observed during the treatment period and at the 18 months follow-up.

Overall study start date
15/09/1999

Completion date
17/01/2006

Eligibility

Key inclusion criteria
1. Patient with diabetes type 1 or 2, with ulcer located on plantar or dorsal site, with an area greater than 2 cm^2
2. Male or female greater than or equal to 18 years old
3. Non-fertile female or fertile females, who use oral contraceptives or intrauterine devices and with a negative pregnancy test
4. Ulcer with Wagner score 1 - 2
5. Patients with transcutaneous partial pressure of oxygen (TcPO2) greater than or equal to 20 mmHg
6. Ulcers without tendency to heal for at least 1 month
7. Ankle branchial index greater than or equal to 0.5

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200 (100 patients for each arm)

Key exclusion criteria
1. Patients who did not give written informed consent
2. Patients with osteomylitis
3. Ulcers with positive bacteriological swabs
4. Patients for whom the use of off-loading device is not recommended
5. Patients who have a re-vascularisation from less than 30 days
6. Patients with serious liver and/or renal insufficiency
7. Patients with malignant neoplasm or diseases with unfavourable prognosis
8. Patients in treatment with corticosteriods, immunosuppressants and/or cytostatic drugs
9. Pregnancy or suspected pregnancy
10. Participation on another clinical trial in foot ulcer treatment during the last two weeks

Only for patients assigned to the treatment group (tissue engineered autografts):
11. Patients who refuse to undergo, prior to study initiation, the following tests: 11.1. Hepatitis B surface antigens (HBsAg)
11.2. Hepatitis C virus (HCV)
11.3. Anti-human immunodeficiency virus 1 (Anti-HIV 1)
11.4. Anti-human immunodeficiency virus 2 (Anti-HIV 2)

Date of first enrolment
15/09/1999

Date of final enrolment
17/01/2006

Locations

Countries of recruitment
Italy

Study participating centre
Via Ponte della Fabbrica 3/B
Abano Terme - Padova
Italy
35031

Sponsor information

Organisation
Fidia Advanced Biopolymers Srl (Italy)

Sponsor details
Via Ponte della Fabbrica 3/B
Abano Terme
Italy
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Sponsor type
Industry

Website
http://www.fidiapharma.com

ROR
https://ror.org/00dy5wm60

Funder(s)

Funder type
Industry

Funder Name
Fidia Advanced Biopolymers Srl (Italy)

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