

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

**Submission date**

24/06/2009

**Recruitment status**

No longer recruiting

**Registration date**

11/08/2009

**Overall study status**

Completed

**Last Edited**

11/08/2009

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☐ Results

☐ Individual participant data

☐ Record updated in last year

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Doriana Senigaglia

**Contact details**

Via Ponte della Fabbrica 3/B

Abano Terme - Padova

Italy

35031

## 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](mailto: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 grown 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<sup>2</sup>
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 (TcPO<sub>2</sub>) greater than or equal to 20 mmHg
6. Ulcers without tendency to heal for at least 1 month
7. Ankle brachial 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 osteomyelitis
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 corticosteroids, 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

35031

## 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