ISRCTN10032417 https://doi.org/10.1186/ISRCTN10032417

Study of the efficacy of an autologous platelet gel for the treatment of diabetic foot ulcers

Submission date
09/11/2021

Recruitment status
No longer recruiting

Registration date
11/11/2021

Overall study status
Completed

Last Edited
17/04/2025

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The RegenKit®-BCT Plus allows the preparation of platelet-rich plasma (PRP) from the patient's own blood by centrifugation. PRP is a preparation of plasma (the liquid fraction of blood) in which platelets (the blood elements responsible for clotting) have been concentrated. PRP is used as a source of growth factors, which are known to play an important role in the wound healing process. For practical reasons, PRP (originally in liquid form) undergoes a gelation step (using a serum also prepared from the patient's own blood to trigger PRP clotting) before it can be applied directly to the wound. The PRP, as well as the serum needed for its gelation are prepared from the patient's own blood, which minimizes the risks of rejection or allergies that are possible with some alternative ulcer treatment procedures. The aim of this study is to evaluate the effectiveness, and the economic merits, of the autologous platelet gel obtained with the RegenKit®-BCT Plus medical device, in comparison to standard care, for the treatment of chronic neuropathic foot ulcers in diabetic patients. A diabetic foot ulcer is an open wound or sore on the skin that's slow to heal. Neuropathic foot ulcers form as a result of a loss of feeling in the feet.

Who can participate?
Patients aged 18 years or older with a chronic neuropathic foot ulcer related to their diabetes

What does the study involve?
Participants are randomly allocated to one of two groups, one of which receives the autologous platelet gel (test treatment) and the other one the standard care of the department (reference treatment). The treatment takes place over a maximum of 6 weeks and consists of autologous platelet gel applied every 2 or 3 weeks, or of the reference treatment according to the usual protocol, depending on the group to which the patient belongs. Compared to the standard care, patients in the platelet gel group must give blood one to three times in order to prepare the platelet gel. Furthermore, the participants have to follow the medical instructions of the investigator and comply with the study design, inform the investigator accurately about the course of the disease and any adverse events, and inform the investigator of any other treatment prescribed by another physician; all preparations purchased by the patient, that are

available without a prescription and/or that are related to alternative medicine (herbs, plants, homeopathic and spagyric essences, Asian therapeutic products, special foodstuffs and vitamins) are also considered to be medicines.

What are the possible benefits and risks of participating?
Participants may access a promising treatment in the field of wound healing under good safety conditions. Indeed, for several years, the autologous platelet gel obtained with RegenKit®-BCT has been evaluated in the Endocrinology and Metabolism Department of the Fondation Hotel-Dieu in Le Creusot, France. The results show that after 6 weeks of treatment, more than 65% of ulcers are completely healed with a treatment based on the use of platelet gels, compared to 50% with the usual treatment. However, the effects of platelet gel application on the ulcer cannot be anticipated.

Where is the study run from?
Fondation Hôtel-Dieu in le Creusot (France)

When is the study starting and how long is it expected to run for?
August 2011 to April 2019

Who is funding the study?
Regen Lab SA (Switzerland)

Who is the main contact?
Dr Bruno Boëzennec
bboezennec@regenlab.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2012-003091-39

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
Regen-2012-WH-001

Study information

Scientific Title
Study of the efficacy of autologous platelet gel obtained with RegenKit®-BCT Plus for the treatment of chronic neuropathic foot ulcers in diabetic patients

Study objectives
To evaluate the efficacy of the autologous platelet gel prepared with RegenKit®-BCT Plus in comparison to standard care with hydrocolloid dressings and to assess its economic merits.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/12/2012, EST I Ethics Committee (ARS de Bourgogne Franche-Comté, Direction de la Santé Publique, Unité d'expertise pharmaceutique et biologique, Le Diapason, 2 place des Savoirs, 21035 Dijon Cedex, France; +33 (0)3 80 42 54 85; cppest1@chlcdijon.fr), ref: N° CPP EST I: 2012/05

Study design
Open-label prospective parallel-group randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Diabetic foot ulcers (grade 3A according to the University of Texas classification)

Interventions
The choice of arm in which each patient are enrolled following their inclusion in the study is defined by a randomisation process known as "per block" via Microsoft Access. This is a method for obtaining the same number of patients in each treatment arm sequentially. Patients are divided into blocks of similar sizes, randomly arranged and within which the distribution of

treatments is also random. This method optimises the "blinding" i.e., the blind allocation of the treatment. Enrolment numbers are allocated in chronological order of patient enrolment.

RegenKit-BCT Plus group:
A platelet gel is prepared using the RegenKit®-BCT Plus (Regen Lab, Le Mont-sur-Lausanne, Switzerland) from a small sample of the patient's blood (24 to 30 ml of blood). This certified medical device contains two RegenBCT tubes for the preparation of a standardized leukocyte poor PRP (Regen® PRP) and one RegenATS tube for the preparation of autologous serum containing activated thrombin (ATS) according to the manufacturer's instructions.
The PRP from two tubes (around 10 ml) is combined with 1 ml of ATS and 1 ml of a 10% injectable solution of calcium gluconate (Monico, Venice Mestre Italy) in a small sterile recipient. After 10 minutes, the resulting platelet gel is ready to be placed on the site to be treated. After application of platelet gel, the wound is covered with a paraffin dressing (Jelonet®, Smith & Nephew SAS, Neuilly-sur-Seine, France), which is fixed in place using permeable dressing tape, e.g., Steristrips (3M, Cergy-Pontoise Cedex, France) in order to keep the wound moist, but also to allow the passage of exudates. The primary dressing is covered with a secondary dressing of sterile gauze to absorb exudates, and bandage, or another means of appropriate fixation. Every week the public health nurse visits the patient at home and removes the secondary dressing to check the primary dressing. If the primary dressing is clean, only the secondary dressing is replaced. In case of any doubt, the nurse contacts the investigators to determine the procedure to follow (opening primary dressing, organizing an appointment at the treatment center, etc). A new platelet gel application is performed when deemed necessary during study treatment visits at the hospital.

Comparative group:
The comparative treatment is the standard local treatment i.e., primary hydrocellular or hydrocolloid dressing (Molnlycke, Wasquehal, France; Hartmann, Selestat, France) and secondary absorbent dressing. In the case of a deep ulcer (pertuis), the wound is packed with sterile non-woven gauze wicking. Depending on the wound, betadine, antibiotics, Collatamp (collagen + antibiotic) (Syntocoll, Germany) are applied. The dressing is initially redone every day for 7 days by a public health nurse at the patient's home. The frequency of subsequent visits at the patient' s home is dependent on the course of the wound healing and treatment continues until the wound is fully healed.

The treatment takes place over a maximum of 6 weeks and consists of autologous platelet gel applied every 2 or 3 weeks, or of the reference treatment according to the usual protocol, depending on the group to which the patient belongs.

Intervention Type
Procedure/Surgery

Primary outcome measure
Percentage of ulcers healed 6 weeks after the first treatment, measured by qualitative assessment of the wound/healing at week 6

Secondary outcome measures
1. The average healing time expressed in days, measured by qualitative assessment of the wound /healing at the end of treatment visit (ETV)
2. The re-epithelialisation level, evaluated on a 5-degree scale (0=absent; 1=mild; 2=moderate; 3=significant; 4=very significant) at each study treatment visit (STV) during the 6 weeks of treatment, at the end of treatment visit (ETV) and at the end of study visit (ESV)

3. Tolerance assessed globally with a 10-point VAS at each study treatment visit (STV) during the 6 weeks of treatment, at the end of treatment visit (ETV) and at the end of study visit (ESV)
4. The degree of acceptability of the treatment by the patient is assessed as very satisfactory, fairly satisfactory unsatisfactory or not satisfactory at all at each study treatment visit (STV) during the 6 weeks of treatment, at the end of treatment visit (ETV) and at the end of study visit (ESV)
5. The economic merits of the treatment estimated a posteriori based on (1) the cost of hospital visits (medical and nursing procedures during the inclusion, treatment and follow-up visits), (2) the cost associated with the follow-up of patients at home by specialized nurses (limited to the period between randomization and the end of treatment) and (3) costs for the material used for care (dressings, RegenKit-BCT Plus, antibiotic treatment when required, off-loading and transport of patients), for the maximum 6-week treatment period as defined in the protocol to which two end-of-study visits are added

Overall study start date
30/08/2011

Completion date
09/04/2019

Eligibility

Key inclusion criteria
1. Diabetic patients, type 1 or 2, aged 18 years or older, with one or more neuropathic ulcers located on the plantar surface of the foot, on the plantar and/or dorsal surface of the toes, grade 3A according to the University of Texas classification, with a surface area of less than 5 cm^2 and a depth of more than 5 mm, and with infection and bone complications (osteitis, shock or bony sequestrum), are treated successfully before inclusion
2. Patients on antiplatelet therapy (Plavix, Sindron, low molecular weight heparin, aspirin, etc) may participate in the study
3. Have signed a free, informed consent form
4. Able to understand the requirements of the trial
5. Patients treated with corticosteroids are included but stratified separately
6. Since the effects of autologous platelet gel prepared with RegenKit®-BCT on the foetus are not known, women of childbearing age may participate in the study, but must use a reliable method of contraception (pill, dual mechanical contraceptive method such as an IUD, diaphragm, etc, in combination with a condom) for the duration of the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

150

Total final enrolment
96

Key exclusion criteria
1. Patients participating in or who have participated in another clinical study within the last 2 months
2. Patients with a history of allergy to a component of the formulation being tested
3. Patients with inherited or acquired haematological or coagulation disorders, such as platelet dysfunction syndrome, critical thrombocytopenia, coagulation disorders, sickle cell disease, etc
4. Anaemic patients (HGB <10 g/dl)
5. Patients with clear clinical signs of acute uncontrolled local or general infection
6. Patients with autoimmune disease (Hashimoto, rheumatoid arthritis, lupus etc)
7. Ulcer whose area has decreased by 20% at the inclusion/randomisation visit compared to the area measured at the screening visit
8. Patients who are not compliant in wound off-loading
9. Patients with malignant disease, particularly with haematological or bone involvement, or metastatic disease
10. Patients on chemotherapy
11. Any other reason which, in the opinion of the investigator, could interfere with the proper conduct of the study

Date of first enrolment
23/04/2013

Date of final enrolment
29/03/2018

Locations

Countries of recruitment
France

Study participating centre
Fondation Hôtel-Dieu
Harfleur Site
Le Creusot
France
71200

Sponsor information

Organisation
Regen Lab SA

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Sponsor type
Industry

Website
https://www.regenlab.com

Funder(s)

Funder type
Industry

Funder Name
Regen Lab SA

Results and Publications

Publication and dissemination plan
Publication is planned (target: Wound Repair and Regeneration Journal). The study protocol is available (in French), but has not been published.

Intention to publish date
31/01/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Regen Lab SA (Dr Bruno Boëzennec, bboezennec@regenlab.com). Full raw (anonymized) data are already available, and retained as long as requested by regulatory requirements. This data will be disclosed on request for regulatory purposes only to health authorities; a publication with results is ongoing. Patients signed an informed consent, including an authorization to disclose their anonymized data.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/04/2025	17/04/2025	Yes	No