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Are diabetic foot ulcers more likely to heal and heal faster when treated with RAPID biodynamic haematogel in addition to usual customary care?

Submission date
31/08/2016

Recruitment status
Suspended

Registration date
31/08/2016

Overall study status
Completed

Last Edited
31/01/2023

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Current plain English summary as of 25/01/2021:
Background and study aims
Some people with diabetes develop diabetic foot ulcers - open wounds or sores on the skin that are slow to heal. This results in huge personal and healthcare costs as well as serious complications such as amputation. The RAPID Biodynamic Haematogel is a gel made from the patient's own blood and the healing factors within it. It works by releasing a concentrated boost of those healing factors into the wound, which restores the patient's own abilities to heal the wound naturally. This study aims to find out whether RAPID Biodynamic Haematogel treatment results in faster healing of these complex wounds.

Who can participate?
Patients aged 18-90 over with diabetic foot ulcers

What does the study involve?
Participants are randomly allocated into two groups. One group receives the best standard treatment while the other group receives the best standard treatment as well as the RAPID treatment. Patients are seen every week for 12 weeks, with one final visit taking place 6 months later.

What are the possible benefits and risks of participating?
Benefits: If participating in the RAPID-1DFU trial, patients will have their wound treated with the best standard of care, irrespective of which arm they are randomised to. Chronic, otherwise unhealing wounds might heal during the trial period.
Risks: Known risks with RAPID™ Gel are possible, such as excessive moisture around the ulcer bed or too much growth of the wound tissue, which may slow healing. There is a chance that the use of the RAPID™ Gel will not help your wound to heal. Known risks with the standard diabetic

ulcer dressings are possible excessive moisture or excessive dryness of the wound bed or too much growth of the wound bed tissue. There is a chance that the use of various dressing types will not help healing.

Where is the study run from?
Biotherapy Services Ltd (UK)

When is the study starting and how long is it expected to run for?
August 2016 to January 2022

Who is funding the study?
Biotherapy Services Ltd (UK)

Who is the main contact?
James Rickard

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Previous plain English summary as of 13/02/2019:
Background and study aims
Some people with diabetes develop diabetic foot ulcers - open wounds or sores on the skin that are slow to heal. This results in huge personal and healthcare costs as well as serious complications such as amputation. A new patented treatment (Aurix) for diabetic foot ulcers that cannot be healed by standard means within six weeks has shown impressive results in the United States. However, this treatment relies on the use of a cow-derived clotting agent (thrombin), which is not allowed in the EU. However, the RAPID Biodynamic haematogel treatment provides the same treatment using the patient's own thrombin. It involves taking blood from the patient and isolating certain blood components (platelets and thrombin). These are mixed together and vitamin C (ascorbic acid) is added. This results in the immediate formation of a gel which is used directly on the wound as a dressing. It works by releasing a concentrated boost of the patient's own wound healing factors which restores the patient's own abilities to heal the wound naturally. This study aims to find out whether RAPID Biodynamic haematogel treatment results in faster healing of these complex wounds.

Who can participate?
Patients aged 18 and over with diabetic foot ulcers

What does the study involve?
Participants are randomly allocated into two groups. One group receives the best standard treatment while the other group receives the best standard treatment as well as the RAPID treatment. Wounds are treated until full wound closure is achieved. Participants allocated to best standard treatment are given the opportunity to move over to the RAPID treatment after 8 weeks if the wound is not healing.

What are the possible benefits and risks of participating?
The RAPID Biodynamic haematogel has shown very good wound healing in previous studies with no side effects. The treatment uses the patients' own blood so the risk is low.

Where is the study run from?
The Royal London Hospital Barts Health NHS Trust

When is the study starting and how long is it expected to run for?
August 2016 to August 2020

Who is funding the study?
Biotherapy Services Ltd (UK)

Who is the main contact?
Janet Hadfield

Previous plain English summary:
Background and study aims
Some people with diabetes develop diabetic foot ulcers - open wounds or sores on the skin that are slow to heal. This results in huge personal and healthcare costs as well as serious complications such as amputation. A new patented treatment (Aurix) for diabetic foot ulcers that cannot be healed by standard means within six weeks has shown impressive results in the United States. However, this treatment relies on the use of a cow-derived clotting agent (thrombin), which is not allowed in the EU. However, the RAPID Biodynamic haematogel treatment provides the same treatment using the patient's own thrombin. It involves taking blood from the patient and isolating certain blood components (platelets and thrombin). These are mixed together and vitamin C (ascorbic acid) is added. This results in the immediate formation of a gel which is used directly on the wound as a dressing. It works by releasing a concentrated boost of the patient's own wound healing factors which restores the patient's own abilities to heal the wound naturally. This study aims to find out whether RAPID Biodynamic haematogel treatment results in faster healing of these complex wounds.

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What are the possible benefits and risks of participating?
The RAPID Biodynamic haematogel has shown very good wound healing in previous studies with no side effects. The treatment uses the patients' own blood so the risk is low.

Where is the study run from?
1. The Barts Health NHS Trust (UK)
2. Ninewells Hospital & Medical School (UK)

When is the study starting and how long is it expected to run for?
November 2016 to October 2017

Who is funding the study?
Biotherapy Services Ltd (UK)

Who is the main contact?
Janet Hadfield

Study website
https://www.rapidstudy.co.uk/

Contact information

Type(s)
Public

Contact name
Mr James Rickard

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Additional identifiers

EudraCT/CTIS number
2018-003596-36

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2.1

Study information

Scientific Title
A Multi-Site, Open Label Randomised Controlled Trial of the RAPID Biodynamic Haematogel Wound Care Treatment in addition to Usual and Customary Care, (UCC); compared to Usual and Customary Care (UCC) alone, in the management of adult patients with chronic Diabetic Foot Ulcers

Acronym
RAPID-1 DFU

Study objectives
Diabetic foot ulcers (DFUs) treated with RAPID© (Restorative Autologous Platelet-derived biotherapies for Injuries and Delayed wound healing) Biodynamic Haematogel + Usual and Customary Care (UCC) are more likely to heal and will heal faster than diabetic foot ulcers treated with UCC alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/10/2018, London City and East Research Ethics Committee (Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT; +44 (0)2071048058; cityandeast.rec@hra.nhs.uk), ref. 17/LO/1372

Study design
Multicentre open-label randomised controlled 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 use contact details to request a participant information sheet

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

Interventions
Current intervention as of 25/01/2021:
The aim of this trial is to demonstrate the effectiveness of complete wound healing in a prospective, open-label, randomised trial in which DFUs will be treated using the RAPID© Biodynamic Haematogel Autologous Platelet Rich Plasma [PRP] treatment in comparison to the usual and customary care [UCC] wound dressing and treatment regimes.

Patients are randomised, using an Advantage eClinical IWRS module, to receive either:
1. The RAPID© Biodynamic Haematogel autologous Platelet Rich Plasma [PRP] treatment + usual and customary care [UCC]
2. Usual and customary care alone

Patients are followed up once per week for 12 weeks, and patients receiving the RAPID© Gel treatment can be treated at each visit (with one extra treatment being provided in the first week), until adequate healing has taken place, to receive a maximum of 13 treatments. Patients then attend a follow up visit 6 months later, for one final review.

Previous intervention as of 13/02/2019:
The aim of this trial is to demonstrate the effectiveness of complete wound healing in a prospective, open-label, randomised trial in which DFUs will be treated using the RAPID© Biodynamic Haematogel Autologous Platelet Rich Plasma [PRP] treatment in comparison to the usual and customary care [UCC] wound dressing and treatment regimes.

Patients are randomised to receive either:
1. The RAPID© Biodynamic Haematogel autologous Platelet Rich Plasma [PRP] treatment every 4-7 days + usual and customary care [UCC]
2. UCC alone

Wounds will be treated until full wound closure is achieved.

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Previous intervention:
The aim of this trial is to demonstrate the effectiveness of complete wound healing in a prospective, open-label, randomised trial in which DFUs will be treated using the RAPID© Biodynamic Haematogel Autologous Platelet Rich Plasma [PRP] treatment in comparison to the usual and customary care [UCC] wound dressing and treatment regimes.

Patients are randomised to receive either:
1. The RAPID© Biodynamic Haematogel autologous Platelet Rich Plasma [PRP] treatment every 4-7 days + usual and customary care [UCC]
2. UCC alone

Wounds will be treated until full wound closure is achieved. Those patients in the UCC not healed after 8 weeks will be offered the opportunity to cross over into the RAPID treatment arm.

Intervention Type
Biological/Vaccine

Phase
Phase II

Drug/device/biological/vaccine name(s)
RAPID© Gel

Primary outcome measure
The proportion of healed DFUs at 12 weeks

Secondary outcome measures
1. Incidence of amputations
2. Proportion of completely healed DFUs
3. Change in the W-QOL (Quality of Life with Chronic Wounds short-form instrument) mean score
4. Visual analogue scale pain score
5. Wound infection
6. Wound complications
7. Cost-effectiveness

Wounds will be examined between 4-7 days until closure of wound. Followed up within 6 months once wound healing achieved.

Overall study start date
01/08/2016

Completion date

30/01/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 25/01/2021:
1. Ability to give informed consent
2. Male or female with confirmed type 1 or type 2 diabetes
3. Aged 18-90 years
4. Diabetic foot ulcer (DFU) measuring more than 0.5 x 0.5 cm and less than 10 x 10 cm, present for more than 12 weeks
5. Only one ulcer present on the affected foot
6. Patient understands and is willing to participate and can comply with the follow-up regime
7. Patient understands and is willing to participate in full Usual and Customary Care (UCC) including recommended off-loading strategy

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Previous inclusion criteria:
1. ≥18 years of age
2. Type I or II diabetes requiring medical treatment as determined by the physician
3. The largest non-healing wound, if multiple wounds are present, or the single wound to be treated (Index Ulcer) is a University of Texas DFU Classification that is located on the dorsal, plantar, medial, or lateral aspect of the foot or heel (including all toe surfaces)
4. For subjects with potentially multiple eligible DFUs, the largest ulcer will be selected as the Index Ulcer for study. There must be at least 4 cm between the Index Ulcer and other ulcers; if all ulcers are closer than 4 cm, the subject should not be enrolled (screen failure)
5. Debrided ulcer size between 0.5 cm2 and 50 cm2
6. Subject has received UCC care for ≥ 2 weeks at treating wound clinic
7. Demonstrated adequate offloading regimen
8. Duration of wound ≥ 1 month at first visit
9. Subject must be willing to comply with the Protocol, which will be assessed by the enrolling clinician
10. The wounds require intervention by a surgeon or specialist clinician
11. Patients must have adequate vasculature, i.e. palpable pedal pulses or in line flow-to-foot on angiogram

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
66

Total final enrolment
66

Key exclusion criteria
Current exclusion criteria as of 25/01/2021:
1. Wound with active infection which simple debridement cannot eradicate including exposed osteomyelitis; however, osteomyelitis of deep unexposed bone treated with antibiotics can be included
2. Patients with underlying vascular insufficiency. (If pedal pulse is absent and ABPI<0.9 or ABPI>1.3, duplex or other arterial imaging will be required to demonstrate in-line flow into the foot).
3. Uncontrolled diabetes mellitus, as measured by an HbA1c >10% (86 mmol/mol)
4. Hb <10.5 g/dl
5. One or more of the following medical comorbidities - hepatic, hematologic, active auto-immune or immune diseases
6. Patient with known or suspected current malignancy
7. Patient not fit for surgery (ASA classification >4)
8. Poor venous access
9. Critical thrombocytopenia
10. Septicaemia
11. Platelet count of <100 x 10(9)/l
12. Serum albumin of <2.5 g/dl
13. Pregnancy

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Previous exclusion criteria:
1. Patients who refuse consent to participate in the study
2. Presence of another wound that is concurrently treated and might interfere with treatment of the index wound by the RAPID© biodynamic haematogel
3. Ulcers not of DFU pathophysiology (e.g., venous, vasculitic, radiation, rheumatoid, collagen vascular disease, pressure, or arterial etiology)
4. Patients on chemotherapeutic agents or any malignancy in the wound area
5. Subjects who are cognitively impaired
6. Serum albumin of less than 2.5 g/dL
7. Plasma platelet count of less than 100 x 10(9)/L
8. Haemoglobin of less than 10.5 g/dL
9. Subject has inadequate venous access for repeated blood draw required for the RAPID biodynamic haematogel administration
10. Abnormal blood clotting dyscrasia, e.g. haemophilia
11. Evidence of bacteraemia, septicaemia or endocarditis

Date of first enrolment
01/03/2019

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal London Hospital
The Barts Health NHS Trust
Whitechapel Road
London
United Kingdom
E1 1FR

Study participating centre
Loughborough Hospital
Leicestershire Partnership NHS Trust
Plaza
Riverside House Bridge Park
Bridge Park Rd
Thurmaston
Leicester
United Kingdom
LE4 8PQ

Study participating centre
Bradford Royal Infirmary
Bradford Teaching Hospitals NHS Foundation Trust
Duckworth Ln
Bradford
United Kingdom
BD9 6RJ

Sponsor information

Organisation
Biotherapy Services Ltd

Sponsor details

59-60 Gainsborough House
Thames Street
Windsor
United Kingdom
SL4 1TX

Sponsor type
Industry

Website
www.biotherapyservices.com

Funder(s)

Funder type
Industry

Funder Name
Biotherapy Services Ltd (UK)

Results and Publications

Publication and dissemination plan
The findings will be reported to the NIHR, the National Institute of Clinical Excellence, the Department of Health and the MHRA. They will also be published in leading academic journals.

Intention to publish date
31/03/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No