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A study to test the effect of a new treatment designed to improve the outcome of infected sockets following tooth extraction.

Submission date	Recruitment status	[_] Prospectively registered
25/11/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/12/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/10/2019	Oral Health	

Plain English summary of protocol

Background and study aims

Dry socket is a common complication that can arise following the extraction of teeth by a dentist (General Dental Practitioner) or a specialist (Oral Surgery Specialist). Dry socket may be defined as the postoperative pain inside and around an extraction site, which increases in severity at any time between the first and third day after the extraction, accompanied by a partial or total disintegration of the blood clot within the tooth socket, with or without smelly breath (halitosis). Sufferers of dry socket usually need postoperative treatment to manage the condition.

The routine treatment for dry socket involves cleaning the area, under anaesthetic if necessary, packing it with a material to soothe the pain and if necessary using a suture (stitch) to hold the material in place while the socket heals. The material used to pack the socket plays an important role in soothing the pain and allowing healing to take place and researchers are always trying to find better more effective materials. A new material that can help the healing of tissue in the mouth following surgery is a product derived from the patients' own blood called PRGF (Plasma Rich in Growth Factors). It has been shown that PRGF enhances tissue healing and also improves the clinical outcomes of various surgical procedures by minimizing postoperative complications such as pain and inflammation/swelling. Venous blood is taken from the patient prior to surgery. The blood is then treated and heated to form a gel like structure which is then inserted at the treatment site. The PRGF then acts on the surrounding tissues to aid healing and regeneration. The aim of this study is to investigate whether PRGF can reduce the pain and improve the healing of dry sockets in patients who have this condition following the extraction of a tooth when compared with a conventional treatment, Alvogyl®.

Who can participate?

Adult dental patients of either gender who have been diagnosed with a dry tooth socket that requires treatment.

What does the study involve?

Patients will be randomly allocated to one of two treatment possibilities: either the use of conventional treatment of Alvogyl® or the use of PRGF.

What are the possible benefits and risks of participating?
While we cannot be sure that the PRGF will improve clinical outcome, previous studies in which PRGF has been used in other oral surgery procedures, such as implant placement, have shown to be beneficial in reducing inflammation and healing times.
The risks in taking part are no greater than those a participant would be exposed to during standard treatment, with some pain or discomfort likely, but normal for this type of procedure.

Where is the study run from?
One single centre, Bristol Dental Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2014 to March 2015

Who is funding the study?
University of Bristol (UK)

Who is the main contact?
Professor Nicola West

Contact information

Type(s)
Scientific

Contact name
Dr Nicola West

Contact details
Clinical Trials Unit (Periodontology)
Bristol Dental School and Hospital
Lower Maudlin Street
Bristol
United Kingdom
BS1 2LY

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
BTI/NW - 0514 (Sponsor Ref: 2319)

Study information

Scientific Title
The effect of Plasma Rich in Growth Factors (PRGF) on the treatment of an infected socket following tooth extraction

Study objectives
Background: Dry socket or alveolar osteitis is one of the most common and unpleasant complications that occurs following the extraction of teeth either by general dental surgeons or by specialist oral surgeons. Dry socket may be defined as the postoperative pain inside and around an extraction site, which increases in severity at any time between the first and third day after the extraction, accompanied by a partial or total disintegration of the blood clot within the tooth socket, with or without halitosis.
Patients usually present with localised severe pain one to three days after extraction. The associated morbidity is detrimental to the patients' social and physical well-being and may last up to 10 days. Aside from the severe morbidity, the impact of dry socket for the patient is that it often requires repeated post-operative treatment visits to manage the condition whereas the impact on the institution providing care is a significant increase in the care logistics and expense. For routine extractions, the incidence of dry socket as a complication is reported to be 0.5-5% while reported rates for third molar (wisdom tooth) removal range from 1-37%. While the data for third molar extraction is somewhat variable, for surgical extractions of impacted molars good evidence exists to suggest dry sockets occur up to 10 times more frequently than for extractions from other locations.
The mechanism of dry socket is not well understood. The fibrin clot that forms inside a tooth socket is thought to lose its integrity and therefore break away. The fibrinolysis is localised and is triggered by the activation of the plasminogen pathway, which in turn is caused by physiologic and non-physiologic substances. The physiologic activators are considered to be released by the alveolar bone within the socket following trauma, whereas the non-physiologic activators are bacterial in origin. Contributory factors include surgical trauma and the difficulty of surgery, lack of operator experience, third molars (wisdom teeth) from the lower jaw, smoking, dislodging the clot post operatively, bacterial infection, excessive curettage of the extraction site, increasing age, and gender (females are affected more than males).

Aim: To investigate the effect of placement of PRGF (marketed as PRGF/Endoret®) as compared to a conventional treatment involving the placement of Alvogyl® on the treatment of dry sockets in patients in which dry socket occurs following extraction. If treatment with PRGF is successful we aim to recommend a PRGF protocol for the routine care of dry socket.
Objectives: The primary objective of this study is to determine whether PRGF (marketed as PRGF /Endoret®) supports the predictable treatment of dry sockets arising after the extraction of teeth by measuring clinical parameters in approximately 40 patients.
The secondary objective is to determine whether the use of PRGF (marketed as PRGF/Endoret®) in the treatment of dry sockets is more effective than a conventional approach alone in improving healing as measured by clinical parameters.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South West - Exeter, 28/10/14, Ref: 14/SW/1101

Study design
This is a single centre, randomised, two treatment regimen, parallel study in dental patients presenting with dry sockets following recent extraction requiring treatment.

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Dry socket or alveolar osteitis

Interventions
Treatment of the dry socket will be performed using debridement and dressing under a local anaesthetic. Following the debridement, the socket will irrigated and plugged with either the Alvogyl® or the PRGF as per the treatment randomisation schedule and then sutured.

Where the socket is randomised to receive the use of Alvogyl®, approximately 0.20g of paste will be inserted to fill the socket as per the manufacturer's instructions. The socket margins will then be sutured.

Where the defect is randomised to receive the use of PRGF (marketed as PRGF/Endoret®), a PRGF clot will be inserted to fill the dry socket. A fibrin membrane will then be applied to cover the surgical area and the socket margins sutured.

The preparation of plasma rich in growth factors (PRGF) will be performed using the PRGF /Endoret®1 dental kit. The PRGF will be collected, processed and administered within a single procedure within the confines of a surgical room where there are no other samples being processed at the same time.

Intervention Type
Procedure/Surgery

Primary outcome measure
Clinical Inflammation score (determined by the clinician):
0 = absence,
1 = slight swelling and hardness,
2 = facial planes blurring without affectation of nasolabial folds or eyes;
3 = facial planes blurring with affectation of nasolabial folds and eyes.

Secondary outcome measures
Pain and patient perceived surgical outcome as determined by Visual Analogue Score (VAS).

Overall study start date

24/11/2014

Completion date
13/03/2015

Eligibility

Key inclusion criteria
1. Consent Demonstrates understanding of the study and willingness to participate as evidenced by voluntary written informed consent and has received a signed and dated copy of the informed consent form
2. Age Aged at least 18 years
3. Compliance Understands and is willing, able and likely to comply with all study procedures and restrictions
4. General Health Good general health with (in the opinion of the investigator) no clinically significant and relevant abnormalities of medical history or oral examination
5. Oral Cavity Have a dry socket following tooth extraction as determined by clinical assessment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
1. Breast-feeding Women who are breast–feeding.
2. Disease
2.1. Current or recurrent disease/dental pathology that could affect the assessments.
2.2. Bleeding disorders.
2.3. Immuno-compromised.
2.4. Current or relevant previous history of serious, severe or unstable physical or psychiatric illness, or any medical disorder that may require treatment or make the participant unlikely to fully complete the study, or any condition that presents undue risk from the study products or procedures.
3. Allergy/Intolerance Known or suspected intolerance or sensitivity to the study materials (or closely related compounds) or any of their stated ingredients.
4. Medication- Any medication which in the Investigators opinion may interfere with the study
5. Clinical Study/Experimental Medication-Participation in another clinical study or receipt of an investigational drug within 10 days of the screening visit.
6. Substance abuse Recent history of alcohol or other substance abuse.
7. Personnel A member of the study site or a family relative. The study site for this protocol is

the Clinical Trials Unit in the Bristol Dental School and Hospital. Employees of the Bristol Dental School and Hospital not associated with the Clinical Trials Unit are eligible to participate.
8. Any patient who, in the judgement of the investigator, should not participate in the study.

Date of first enrolment
24/11/2014

Date of final enrolment
27/02/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Dental School and Hospital
Clinical Trials Unit
Lower Maudlin Street
Bristol
United Kingdom
BS1 2LY

Sponsor information

Organisation
University of Bristol

Sponsor details
Senate House
Tyndall Avenue
Bristol
England
United Kingdom
BS8 1TH

Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Not defined

Funder Name
University of Bristol (UK)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

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	01/06/2018		Yes	No
HRA research summary			28/06/2023	No	No