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The effect of Emdogain on changes in cytokine profile during early wound healing

Submission date
22/02/2016

Recruitment status
No longer recruiting

Registration date
22/02/2016

Overall study status
Completed

Last Edited
22/02/2016

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Periodontitis is a serious gum infection that damages the soft tissue and bone that supports the teeth (periodontium). It is caused by bacteria which attach to the teeth at the gum line and cause an infection. Over time, the bacterial infection causes inflammation (swelling) and pain in the mouth, eventually leading to tooth loss if it is not properly treated. The condition is largely preventable by good oral hygiene (brushing and flossing morning and night) however if the periodontitis is particularly advanced then more drastic treatment is necessary. Emdogain is a product which was introduced in 1996 to treat gum disease, usually in combination with dental surgery. It is an enamel matric derivative (EMD) which means that it is able to stimulate the soft tissues and bone surrounding the teeth the regrow (regeneration). Several studies have shown that Emdogain can be very effective an promoting regeneration of the periodontium, however the way that this works is still not fully understood. The aim of this study is to assess the effects of treatment using Emdogain on cytokine (chemicals naturally produced by the body which help wound healing) levels in the pockets around the teeth.

Who can participate?
Non-smoking adults aged between 25 and 75 who are suffering from gum disease with two teeth in different areas of the mouth requiring surgical treatment.

What does the study involve?
All participants have two teeth in different parts of their mouth which require surgical treatment. For both teeth, the gum is cut open to expose the bone so that a deep-cleaning can be completed to remove the bacteria and plaque that is causing the infection. The two teeth in each participant's mouth are randomly allocated to two groups, in which those in the first group undergo the open flap debridement only and those in the second group have 0.3ml of Emdogain applied to the tooth root surface and the affected part of the periodontium at the end of the open flap debridement procedure. A sample of ginvival fluid (fluid around the gum line) is taken from the top of each tooth at the start of the study and then again after 7 and 14 days to measure levels of cytokines.

What are the possible benefits and risks of participating?
There is a possibility that the areas treated using Emdogain may help to promote tissue

regeneration following surgery. There is a small risk of discomfort and tenderness following surgery, however this is usual after this type of procedure.

Where is the study run from?
Bjerke Tannmedisin (Norway)

When is the study starting and how long is it expected to run for?
January 2014 to September 2014

Who is funding the study?
1. Norwegian Research Council (Norway)
2. Institute of Clinical Dentistry, University of Oslo (Norway)

Who is the main contact?
1. Professor Janne Elin Reseland (scientific)
2. Dr Oscar Villa (scientific)

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2013/1821/REK sør-øst C

Study information

Scientific Title
Enamel matrix derivatives in periodontal regenerative surgery modulates cytokine profiles: A randomised controlled clinical trial

Study objectives
Null hypothesis:
The enamel matrix derivative does not differentiallly induce cytokine profiles in vitro and clinically compared to the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Norwegian Medicines Agency and the Regional Committees for Medical and Health Research Ethics, 20/11/2013, ref: 2013/1821/REK sør-øst C

Study design
Single-centre randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Generalized severe chronic periodontitis

Interventions
All participants present two teeth in different regions of the mouth that require surgical treatment. One of these teeth is randomly selected to undergo open flap debridement with the

application of Emdogain (intervention) and the other tooth undergo the same surgical procedure but without the application of Emdogain. The dosage given is 0.3ml of Emdogain to a concentration of 30 mg ml-1, applied one time at the time of the surgery onto the root surface and the periodontal defect.

The follow-up period for both the control and intervention teeth is two weeks, with samples of gingival fluid tested for cytokines at 7 and 14 days.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Enamel matrix derivative

Primary outcome measure
Cytokine levels in gingival fluid are measured using the Luminex-200 system (multiplex bead-based immunoassay) at baseline, 7 and 14 days postoperatively.

Secondary outcome measures
N/A

Overall study start date
01/01/2014

Completion date
05/09/2014

Eligibility

Key inclusion criteria
1. Aged between 25 and 75 years
2. Non-smoking
3. No use of antibiotics over the previous 6 months prior to treatment
4. The presence of one pair of interproximal sites with probing pocket depth (PPD) of 6 mm or more, horizontal and/or vertical bone loss as demonstrated by the probing measurement and radiographic assessments following the initial phase of periodontal treatment
5. Experimental teeth must either have a vital pulp or, if subjected to root canal treatment, be asymptomatic, and without technical remarks
6. Prior to the start of the trial, the patients will give informed consent

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
15

Key exclusion criteria
1. Patients with a systemic condition like diabetes mellitus, cancer, HIV, disorders that compromise wound healing, chronic high dose steroid therapy, bone metabolic disease, radiation or immune-suppressive therapy
2. Patients with acute infectious lesions in the area of intended therapy

Date of first enrolment
01/01/2014

Date of final enrolment
15/04/2014

Locations

Countries of recruitment
Norway

Study participating centre
Bjerke Tannmedisin
Trondheimsveien 275
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N-0589

Sponsor information

Organisation
Regional Committees for Medical and Health Research Ethics (REK)

Sponsor details
Gullhaugveien 1-3
Oslo
Norway
0484

Sponsor type
Other

Website
http://helseforskning.etikkom.no

ROR
https://ror.org/00srhwt80

Funder(s)

Funder type
Government

Funder Name
Norwegian Research Council (Norges Forskningsråd)

Alternative Name(s)
Forskningsrådet, Norwegian Research Council, Research Council of Norway

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Norway

Funder Name
Institute of Clinical Dentistry, University of Oslo

Results and Publications

Publication and dissemination plan
Planned publication in the journal Scientific Reports.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request