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

	Recruitment status	Prospectively registered
	No longer recruiting	☐ Protocol
Registration date 22/02/2016	Overall study status Completed	Statistical analysis plan
		Results
Last Edited	5 5	Individual participant data
22/02/2016		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

Type(s)

Scientific

Contact name

Prof Janne Elin Reseland

Contact details

Institute of Clinical Dentistry Department of Biomaterials Geitmyrsveien 71 Oslo Norway 0455

Type(s)

Scientific

Contact name

Dr Oscar Villa

Contact details

Institute of Clinical Dentistry Department of Biomaterials Geitmyrsveien 71 Oslo Norway 0455

Additional identifiers

Protocol serial number

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 differentially 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

N/A

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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 Oslo Norway N-0589

Sponsor information

Organisation

Regional Committees for Medical and Health Research Ethics (REK)

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, The 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes