A Single-Center, Single-Cohort Study of FF-37101 for Bone Formation in the Maxillomandibular Region

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24676

Source
NTR

Brief title
TBA

Health condition

Reduction of Jawbone

Sponsors and support

Primary sponsor: Fujifilm Manufacturing Europe BV
Source(s) of monetary or material Support: Company

Intervention

Outcome measures

Primary outcome

Primary performance endpoint: The proportion of patients that has bone formation assessed based on bone height measurements, in the grafted site after 6 months, as identified by CBCT imaging.

Secondary outcome

Secondary performance endpoint:
1) The evidence of newly formed bone and its individual components, bone maturity, and soft tissue/marrow space, at 6 months post-treatment, identified by histologic analysis of biopsies of the pre-molar and molar teeth.

Exploratory performance endpoints:
1) The amount of bone that has been formed in the extraction socket assessed based on bone height measurements, at 3 months post-treatment, identified by CBCT evaluation.
2) The amount of FF-37101 at 6 months post-treatment, identified by histologic analysis of biopsies of the pre-molar and molar teeth.
3) The implant stability quotient (ISQ) that is measured after placing the implant, identified by ISQ measurement devices.
4) The bone volume that has been formed in the extraction socket at 3 and 6 months post-treatment, identified by CBCT evaluation.

Study description

Background summary

This study is a single center, single cohort, non-randomized, open label clinical study to demonstrate the performance and safety of FF-37101, intended to support new bone formation in the maxillomandibular region. The study will target to implant 30 subjects with FF-37101 in order to follow at least 23 subjects for 6 months post-treatment.

Study objective

A one-sided exact binominal test of proportions will be used to determine if the proportion of patients (π) that have bone formation assessed based on bone height measurements, in the grafted site after 6 months, as identified by CBCT imaging, will be greater than 50%. If the p-value from this test is less than or equal to 0.05 then we will state that there is significant evidence to reject the null hypothesis that the proportion is less than or equal to 50% in favor of the alternative that the proportion is greater than 50%.

Study design

0, 1 week, 2 weeks, 1 month, 2 months (phone contact), 3 months, 6 months

Intervention

Use of FF-37101 as bone graft scaffold after tooth extraction

Contacts

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Eligibility criteria

Inclusion criteria

• Ability to understand the purpose and risks of the study and provide signed and dated informed consent and authorization.
• 18 year or older at time of informed consent.
• Have 1 tooth (front, pre-molar or molar) of poor prognosis diagnosed for tooth extraction.
• Have 1 or more healthy tooth/teeth immediately adjacent to the tooth that is to be extracted.
• Have a type I or type II socket of the buccal alveolar bone of the tooth to be extracted.
• Absence of pockets of 5mm or more in the full dentition, with exception of the pocket of the tooth to be extracted.
• Able to return for follow-up visits, as defined in this clinical investigation plan, after tooth extraction.
• Scheduled to have an implant placed 6 months after tooth extraction and FF-37101 implantation.

Exclusion criteria

• Signs of active inflammation, i.e. presence of inflammatory fluid during tooth extraction.
• Active generalized periodontal disease; evident periapical radiolucencies or abscesses; autoimmune disorders; taking or having a history of bisphosphonate medications or Denosumab (history of MRONJ (medication-related osteonecrosis of the jaw)/BRONJ (bisphosphonate-related osteonecrosis of the jaw)); congenital or metabolic bone disorders; or uncontrolled diabetes.
• Full coverage restoration or large metallic restoration work including dental implant completed on any tooth adjacent to the tooth to be extracted in this clinical investigation.

• Current or former smoker or user of chewing tobacco or nicotine-containing products. Former smokers or users are defined as subjects who smoked 10 cigarettes or more (or an equivalent amount of other tobacco products) per day in the 5 years prior to screening.
• Females who are pregnant, breastfeeding, or are planning to conceive during their enrollment in the clinical investigation.
• History of any clinically significant mental and/or psychological, or other major disease, as determined by the investigator that would prevent dental treatment.
• Inability to effectively communicate with study staff during the clinical investigation.
• History of any severe allergic or anaphylactic reactions to collagen or gelatin, or current sensitivity to collagen or gelatin.
• Unwillingness or inability to comply with the requirements of this clinical investigation plan.
• Previous head and neck radiation- or chemo-therapy.
• Other reasons that, in the opinion of the investigator, will make the subject unsuitable for enrollment.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2020
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 07-02-2020
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55475
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8363
CCMO	NL65005.028.19
OMON	NL-OMON55475

Study results